PB-225 333

SOLID WASTE MANAGEMENT IN THE DRUG INDUSTRY

LITTON SYSTEMS, INC.

PREPARED FOR
ENVIRONMENTAL PROTECTION AGENCY

1973

Distributed By:

NTIS
National Technical Information Service
U. S. DEPARTMENT OF COMMERCE

PB 225 333

SOLID WASTE MANAGEMENT IN THE DRUG INDUSTRY

This publication (SW-44c) was written
for the Federal solid waste management programs
by DONALD M. SHILESKY, KLAUS W. KRAUSE, *and* RALPH J. SULLIVAN
Litton Systems, Inc., Camarillo, California
under Contract No. CPE 69-7
and is reproduced as received from the contractor

Reproduced by
NATIONAL TECHNICAL
INFORMATION SERVICE
U S Department of Commerce
Springfield VA 22151

U.S. ENVIRONMENTAL PROTECTION AGENCY
1973

115

310148

This report has been reviewed by the U.S. Environmental Protection Agency and approved for publication. Approval does not signify that the contents necessarily reflect the views and policies of the U.S. Environmental Protection Agency, nor does mention of commerical products constitute endorsement or recommendation for use by the U.S. Government.

An environmental protection publication (SW-44c) in the solid waste management series

BIBLIOGRAPHIC DATA SHEET	1. Report No. EPA/530/SW-44c	2.	3. Recipient's Accession No. PB-225 333
4. Title and Subtitle Solid waste management in the drug industry			5. Report Date 1973 6.
7. Author(s) Donald M. Shilesky, Klaus W. Krause, and Ralph J. Sullivan			8. Performing Organization Rept. No.
9. Performing Organization Name and Address Litton Systems, Inc. 4667 Telegraph Rd. Camarillo, California 93003			10. Project/Task/Work Unit No. 11. Contract/Grant No. CPE 69-7
12. Sponsoring Organization Name and Address U.S. Environmental Protection Agency Office of Solid Waste Management Programs Washington, D.C. 20460			13. Type of Report & Period Covered Final report 14.
15. Supplementary Notes			

16. Abstracts This report provides a description and analysis of solid waste management in the drug industry. A general description of the industry is presented followed by a description of the products and production processes of the industry. The solid wastes produced by 29 interviewed establishments are tabulated and the relationship between employment number and solid waste generated is evaluated. An analysis is made of solid waste management practices, economics, aesthetics, and future trends. Recycling possibilities are evaluated; and envolvement of government agencies is discussed. The impact of waste production on surrounding communities is assessed.

Conclusions indicating the present situation, possible future trends and developments, and recommendations for further study are presented.

17. Key Words and Document Analysis. 17a. Descriptors

Drug industry, incineration, industrial waste, collection, pharmaceuticals, surveys, recycling, disposal

17b. Identifiers/Open-Ended Terms

Resource recovery, sanitary landfill, pretreatment

17c. COSATI Field/Group 13B

18. Availability Statement	19. Security Class (This Report) UNCLASSIFIED	21. No. of Pages 112
	20. Security Class (This Page UNCLASSIFIED	22. Price 4.25

AUTHORS' PREFACE

This report on a study of Industrial Solid Waste Management in the Drug Industry was prepared by Litton Environmental Systems Division, Camarillo, California, under Office of Solid Waste Management Programs (formerly Bureau of Solid Waste Management) Contract No. CPE 69-7. The statements, findings, conclusions, recommendations, and other data in this report do not necessarily reflect the views of the U.S. Environmental Agency, nor does mention of commerical products imply endorsement by the U. S. Government.

The principal investigator was Mr. Donald M. Shilesky. Mr. Ralph J. Sullivan was Project Manager. Valuable consultant services were provided by Dr. Edwin E. Hays and staff support by Mr. Marvin L. Feuerborn and Mr. Klaus W. Krause.

The initial efforts of Dr. Joe Goeppner, former Litton Project Manager for this study, effectively provided the basic groundwork on which the study rests. In addition, we would like to acknowledge the efforts of Mr. Michael L. Senske and Mr. Rodney L. Cummins, Project Officers for the Office of Solid Waste Management Programs.

Finally, we are pleased to acknowledge the generous cooperation of the interviewed companies in supplying requested information and in providing helpful guidance during the conduct of this study. Responsibility for any errors or omissions, however, rests fully on us.

TABLE OF CONTENTS

	Page
List of Tables	
List of Figures	
Definition of Key Terms	
Summary	1
Introduction	4
Description of Industry	6
SIC Codes	6
Geographical Distribution	7
Size	9
Employment	11
Total Plant Production and Plant Value for Industry	12
Sales	12
Net Worth	15
Summary	15
Production Patterns	16
Past	16
Future	18
Products and Processes	21
Production Processes	21
Products Marketed	28
Analysis of Development and Production Patterns	30
Methods and Procedures	32
Method of Sample Selection	32
Type of Questionnaire	36
Interview Format	36
Reliability of Information	37
Data Analysis and Presentation	38
General	38
Solid Wastes	44
Sources	44
Types and Quantities	44

Page

Data Analysis and Presentation (continued)

Comparison of Waste Generation with Employment..... 47

Solid Waste Management..... 50

Analysis of Collection and Disposal Systems..... 50

Practices..... 50

Economics..... 54

Aesthetics..... 58

Future..... 58

Present Recycling Possibilities..... 59

Involvement of Governmental Agencies..... 61

Influence on Surrounding Communities..... 62

Conclusions..... 64

References..... 69

Appendix A - Summary of Solid Waste Literature..... 72

Appendix B - Bibliography..... 75

Appendix C - Questionnaire..... 83

LIST OF TABLES

Table		Page
1	Geographical Distribution	10
2	Manufacturing Processes Reported	21
3	Distribution of Drug Companies by Employment and Major Regions	33
4	Frequency of Questionnaire Responses	39
5	Summation of Solid Waste Quantities and Management Costs (Sheet 1)	41
5	Summation of Solid Waste Quantities and Management Costs (Sheet 2)	42
6	Frequency of Reported Solid Waste Types	45
7	Pounds per Day - SIC 2833	46
8	Pounds per Day - SIC 2834	46
9	Comparison of Total Solid Waste Generated with Employment	48
9A	Methods of Solid Waste Disposal at 29 Pharmaceutical Plants.....	51
10	Waste Management Costs and Employment	56
11	Waste Management Costs by Geographical Region	57

LIST OF FIGURES

Figure		Page
1	Geographical Distribution of the Drug Industry	8
2	Production of Biologicals	23
3	Production of Medicinal Chemicals	23
4	Production of Synthetic Medicinal Chemicals	23
5	Production of Botanical Products	25
6	Production of Tablets	25
7	Production of Capsules	25
8	Production of Liquid Preparations	27
9	Production of Salves or Ointments	27
10	Production of Aerosols	27
11	Flow Diagram of Solid Wastes in the Drug Industry ..	40

DEFINITION OF KEY TERMS

1. Drug industry: that segment of U.S. manufacturing activity which produces medicinal chemicals, pharmaceutical products, and biological and botanical products used for medicinal purposes. Pharmaceutical industry is generally used as an interchangeable term. (See definition of SIC Codes.)

2. Ethical drugs: drugs promoted primarily to the medical profession. Almost all ethical drugs are available only by prescription, though a few are available over the counter.

3. Geographical regions: regions used by U.S. Department of Commerce in defining geographical distribution of manufacturers and SIC code production. Referred to by letter and title as follows:

A.	New England:	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
B.	Middle Atlantic:	New Jersey, New York, Pennsylvania
C.	South Atlantic:	Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
D.	East North Central:	Illinois, Indiana, Michigan, Ohio, Wisconsin
E.	East South Central:	Alabama, Kentucky, Mississippi, Tennessee
F.	West South Central:	Arkansas, Louisiana, Oklahoma, Texas
G.	West North Central:	Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
H.	Mountain:	Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
I.	Pacific:	Alaska, California, Hawaii, Oregon, Washington

4. Production wastes: 1) Mixed wastes comprise miscellaneous scrap resulting from production processes, e.g., paper, glass, metal, and plastic scrap. 2) Process wastes comprise those solid wastes more or less characteristic of drug-producing processes, e.g., reject drugs (see definition), fermentation cake, chemical dust, spent botanical and biological tissue.

5. Proprietary drugs: drugs promoted primarily to the general public and available for purchase without prescription.

6. Rejects or rejected products: products removed during production or quality control inspection because of defects.

7. Returned products: defective or expired products returned from marketing channels or consumers.

8. Salvage: the process of removing material from the waste flow for purposes of reuse or byproduct production. The term is used interchangeably with recycling and reclamation.

9. SIC Codes: are defined for the drug industry in the Standard Industrial Classification Manual (published by the Bureau of the Budget) as follows:

   SIC 2831 - Biological Products. Establishments primarily engaged in the production of bacterial and virus vaccine, toxoids and analogous products (such as allergenic extracts), serums, plasmas, and other blood derivatives for human and veterinary use.

   SIC 2833 - Medicinal Chemicals and Botanical Products. Establishments primarily engaged in (1) manufacturing bulk organic and inorganic chemicals and their derivatives; and (2) processing (grading, grinding, and milling) bulk botanical drugs and herbs. Establishments primarily engaged in manufacturing agar-agar and similar products of natural origin,

endocrine products, manufacturing or isolating basic vitamins, and isolating active medicinal principals such as alkaloids from botanical drugs and herbs.

SIC 2834 - Pharmaceutical Preparations. Establishments primarily engaged in manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use. The greater part of the products of these establishments are finished in the form intended for final consumption, such as ampoules, tablets, capsules, ointments, medicinal powders, solutions, and suspensions. Products of this industry consist of two important lines, namely: (1) pharmaceutical preparations promoted primarily to the dental, medical, or veterinary professions; and (2) pharmaceutical preparations promoted primarily to the public.

ABSTRACT

This report provides a description and analysis of solid waste management practices in the drug industry as presented by 29 pharmaceutical plants in different geographical locations. A general description of the industry, including size, geographical distribution, and past and future production patterns, is presented, followed by a description of the products and production processes of the industry. Some suggestions of possible future developments in these areas are also presented. The methods and procedures applied in the study are described.

The solid wastes produced by these 29 establishments are tabulated as to sources, types, and quantities. The relationship between employment number and solid waste generation is also evaluated; however, there appears to be little discernible association. An analysis is made of solid waste management practices (principally incineration, hauling off site, off-site land disposal), economics (average cost for total solid waste management is about $14/ton), aesthetics, and future trends at the interviewed plants. Present recycling possibilities are evaluated and found to be few; and involvement of government agencies is discussed, as well as the impact of waste production at the 29 plants on their surrounding communities.

Conclusions indicating the present situation, possible future trends and developments, and recommendations for further study are presented.

This report was submitted in fulfillment of Contract No. CPE 69-7 between the Office of Solid Waste Management Programs (EPA) and Litton Environmental Systems, a division of Litton Systems, Inc.

SUMMARY

A general growing concern over pollution on a national scale is the background for this study of solid waste management in the drug industry. Mounting volumes of industrial and municipal wastes, combined with a shrinking number and capacity of disposal sites, present a potential national crisis.

Depending on definition of the term, the "drug industry" includes between 2,000 and 3,000 production and processing facilities. In 1967 about 130,000 employees were directly involved in drug production; however, depending on the definition used, total employment in the pharmaceutical industry is somewhere between that figure and upwards of a million. The industry accounted for 1 to 1½ percent of 1967 sales volume for all U.S. manufacturing activites. In this study, data were obtained from 29 establishments chosen to provide a representative sample of the industry. A questionnaire provided the structural format for an interview of company representatives. The reliability of the quantitative data, however, is in question because accurate company records were not kept for the activities of interest.

With some exceptions, pharmaceutical company wastes were found to approximate the composition of municipal refuse (paper, cardboard, plastic, glass, metal, garbage, etc.). The major differences occurred in the generation of spent solid materials from fermentation processes and biological and botanical extraction operations and in waste chemicals and returned products. Little relationship was found to exist between number of employees and amount of waste generated. Calculations based on the larger interviewed plants suggest average generated waste loads of about 25 lb/day per employee and about 70 lb/day per production employee. Because of disparities in figures for various total employment sizes, caution is recommended in extrapolating these waste loads to totals for the industry. These disparities also

suggest that types of production processes are more likely to prove useful than employment number as parameters to correlate with waste quantities.

Present waste management practices consist primarily of disposal by hauling to off-site land disposal and of on-site incineration. Since a pharmaceutical plant could use both hauling from premises and incineration as methods of solid waste handling, the data relating to these practices at the surveyed plants overlap to a considerable extent. Therefore, 97 percent of these plants practiced hauling from premises, and 52 percent of these same facilities also performed incineration.

Costs of collection and hauling account for the greatest percentage of total expenses for waste management (about 82 percent). Attempts at salvage, made by 27.6 percent of the interviewed plants, are nearly always limited to recovery of cardboard packaging material. Tabulated statistics show great disparities in costs for solid waste management and are considered unreliable, again because of inadequately detailed company records. A calculated average annual cost of about $14 a ton for total solid waste management appears to be reasonable. Costs in the Middle Atalntic region, however, were more than twice as high as those in the East North Central region. Cost vs employment figures indicate that companies whose production is characterized by more than one SIC code show a significatnly lower average annual cost per employee than those producing in only one SIC code, but no other clear trends appear.

Aesthetically, in-plant solid waste treatment and disposal practices are conscientiously neat and are generally designed to be inconspicuous or to offend as little as possible. Most plants prefer, however, to have most of their waste hauled away from the plant site for disposal by others. Recycling possibilities appear to be few, based on present economic and technological realities. The direct impact of company disposal practices on surrounding communities seems to be confined

to the general problem of adding large quantities of wastes to limited disposal sites.

Regulation by government agencies consists primarily of supervision over handling of narcotics and radioactive wastes, of air pollution requirements for incineration, and of regulated contract hauling and dumping practices. Less than half of the companies were aware of any comprehensive governmental planning which includes their solid waste production.

In general, this study presents a reliable qualitative picture of present waste management practices in the drug industry. Quantitative data are included and are roughly indicative of the scope of the operations, but their direct use is cautioned against because of a lack of accurate records kept at the company level. This deficiency indicates a strong requirement for definitive on-site studies of generated waste quantities and of costs for waste treatment and disposal.

INTRODUCTION

Concern over lack of knowledge about quantities and types of existing solid wastes, and about the methods of handling and disposing of these solid materials, is becoming prevalent in today's society. Production of two major categories of solid waste (municipal and industrial) is causing local, state, and federal governments to seek relief from the annual increase in the quantities of solid wastes. Disposal methods and sites are becoming more scarce each day. Recent legislation passed by Congress is intended to give some relief to this situation by promoting the recycling of solid wastes, both municipal and industrial. Prior to this act of Congress, detailed studies had been made of municipal solid wastes (quantities, types, handling, and disposal); however, very little definition of specific industrial solid wastes has been documented. This study, one of a series on industrial solid wastes, is designed to give the Federal solid waste management program insight into the solid waste sources, types, quantities, handling, disposal, and management costs for the pharmaceutical industry as defined by U. S. Bureau of the Budget, SIC (Standard Industrial Classification) codes 2831, 2833, and 2834. (See page 6.)

This report reviews the solid waste management of 29 of the 2,000 + pharmaceutical plants, representing small, medium, and large companies producing biological products (SIC 2831), medicinal chemicals and botanical products (SIC 2833), and pharmaceutical preparations (SIC 2834). An endeavor is made to describe the industry according to its SIC codes, size, employment, geographical distribution, production patterns, and plant value. Typical product and process diagrams are included to give an understanding of the manufacturing practices and an indication of solid waste problems. Detailed diagrams and discussions of solid waste management with respect to production processes in the pharmaceutical industry are portrayed throughout the report. Pertinent findings and data interpretations are included in the conclusions.

A search of entries in the Engineering Index (1929-1969) and the Business Index (1945-1969) showed that published information on solid wastes management in the drug industry is scarce. A considerable number of articles and publications dealing with other aspects of the industry were found, and these are listed in the bibliography (Appendix B). Some of these publications were helpful in developing the background and financial picture which make up part of this report. Even these, however, suffer from a chronic case of ambiguity or even outright contradiction when taken as a group. Attempts to draw consistent and reliable information from these sources were hampered by use of common but poorly defined (or undefined) terms, by discrepancies in quoted statistics, and at times by lack of objectivity in presentations clearly designed to serve special interests. Government publications, on the other hand, suffer primarily from lack of currency in data and secondarily from limited scope of coverage.

Eleven articles have been found which deal specifically with solid waste management in the drug industry. Seven of these describe practices at Lederle Laboratories, a division of American Cyanamid Company, from 1945 to 1968; three deal with Eli Lilly and Company, and one with G.D. Searle and Company. Appendix A contains a brief description of each of these articles.

The need for objective, factual, and detailed studies in this area is evident. This report addresses itself to that need.

DESCRIPTION OF INDUSTRY

SIC CODES

The Standard Industrial Classification (SIC) Manual[1] describes a system of industrial classification developed over a period of years by experts on classification in government and private industry under the guidance of the Bureau of the Budget.

Under the SIC system, the categories of pharmaceutical manufacturers are defined by three four-digit code numbers:

SIC 2831 Biological Products
SIC 2833 Medicinal Chemicals and Botanical Products
SIC 2834 Pharmaceutical Preparations

These are subclassifications of SIC Group 283 (Drugs), which comes under SIC Major Group 28 (Chemicals and Allied Products). Assignment of the three industry codes is made according to the following definitions:

SIC 2831 - Biological Products. Establishments primarily engaged in the production of bacterial and virus vaccine, toxoids and analogous products (such as allergenic extracts), serums, plasmas, and other blood derivatives for human and veterinary use.

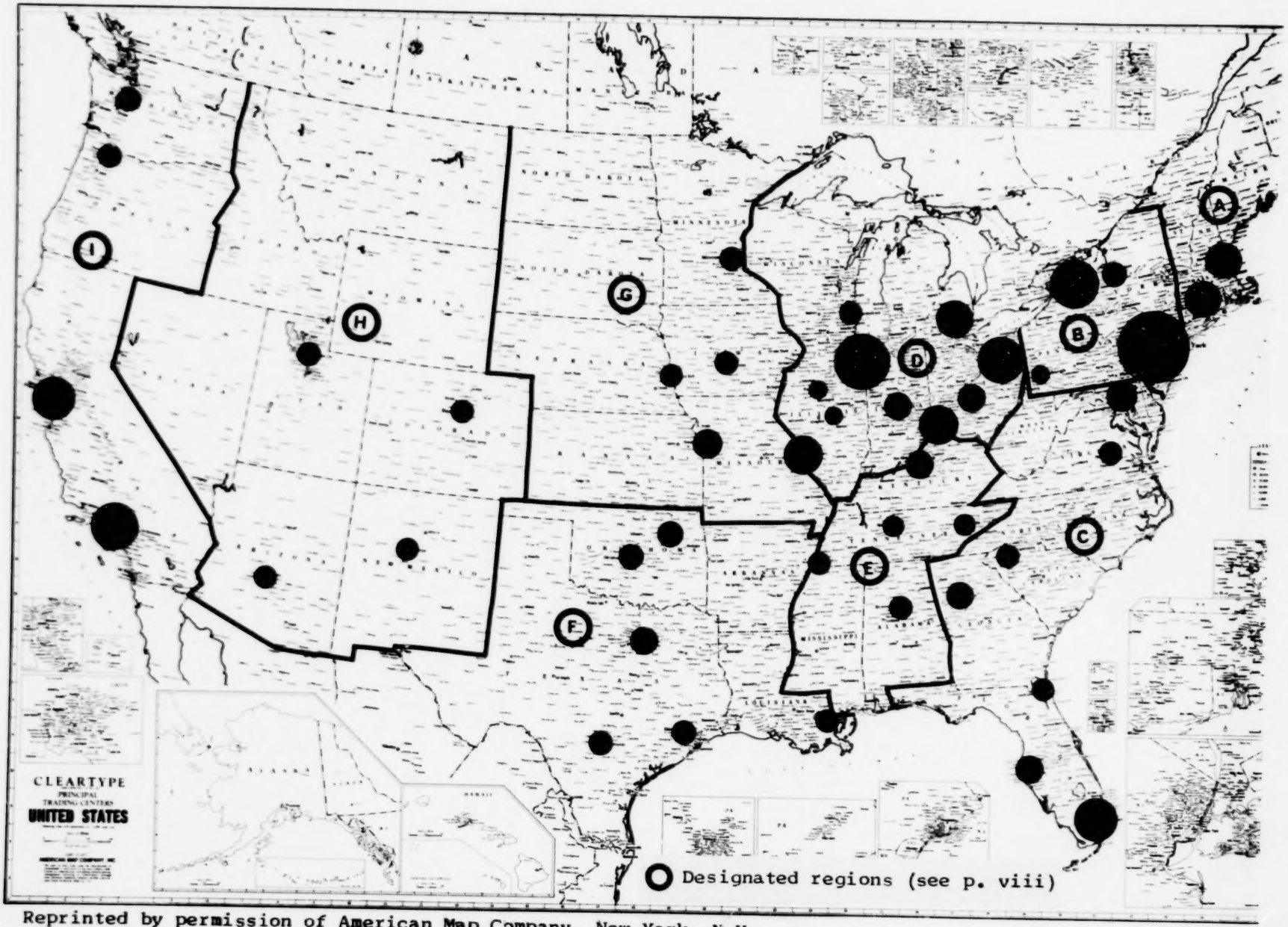
SIC 2833 - Medicinal Chemicals and Botanical Products. Establishments primarily engaged in (1) manufacturing bulk organic and inorganic chemicals and their derivatives; and (2) processing (grading, grinding, and milling) bulk botanical drugs and herbs. Establishments primarily engaged in manufacturing agar-agar and similar products of natural origin, endocrine products, manufacturing or isolating basic vitamins, and isolating active medicinal principals such as alkaloids from botanical drugs and herbs.

SIC 2834 - Pharmaceutical Preparations. Establishments primarily engaged in manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use. The greater part of the products of these establishments are finished in the form intended for final consumption, such as ampoules, tablets, capsules, ointments, medicinal powders, solutions, and suspensions. Products of this industry consist of two important lines, namely: (1) pharmaceutical preparations promoted primarily to the dental, medical, or veterinary professions; and (2) pharmaceutical preparations promoted primarily to the public.

GEOGRAPHICAL DISTRIBUTION

Information in this section is derived from Dun and Bradstreet statistics[2] and from Drug Topics Red Book 1969[3] and Drug Topics Red Book Cumulative Supplement #2 (May 1969).[4] The Dun & Bradstreet list includes 2082 companies with primary and secondary production in one or more of the three SIC codes (specified for 2059 of them). Companies listed from the Red Book and its supplement are not characterized by SIC code and represent a less definite sector of the drug industry, since the extent of their involvement in production of SIC 2831, 2833, and 2834 is unknown.

Numerically, the drug industry is concentrated primarily in the Middle Atlantic region (New York, New Jersey, Pennsylvania), with strong representation in the East North Central (mainly Illinois) and Pacific (mainly California) regions (Figure 1). These three regions contain about 65 percent of the drug companies, with the five named states accounting for over 50 percent of the total. Overall, 2,889 drug producers have been tabulated, with 2,059 of these known to produce SIC 2831, 2833, or 2834 products. These figures represent actual numbers of companies; those involved with more than one of the three SIC codes have been counted only once. The complete listing includes companies operating in 47 states and the District of Columbia.



Reprinted by permission of American Map Company, New York, N.Y.

Figure 1. Geographical Distribution of the Drug Industry
(Shaded circles correspond roughly to areas of concentration.)

Table 1 summarizes the Dun and Bradstreet and Red Book data representing the geographical distribution of the drug industry. The following sample calculation for Region B demonstrates the significance of the percentage figures in Table 1:

Companies known to produce in one or more of the three SIC codes:	712
"Drug Companies" for whose products SIC codes are not known:	292
Total for both types of company:	1,004

Thus Region B has $\frac{712}{2059}$ or 34.6% of the "3 SIC" companies

$\frac{292}{830}$ or 35.2% of the "Unknown" companies

$\frac{1004}{2889}$ or 34.8% of the "Total Drug" companies

SIZE

The nature of the drug industry is such that a determination of its "size" in an absolute sense becomes nearly impossible. Any final judgment depends heavily on the parameters (e.g., sales and employment figures for drug products and non-drug products, domestic and foreign sales figures) that are included or excluded from consideration. The term "drug industry" is commonly used in two senses:

1. Restricted definition: a) Companies whose primary products fall into one or more of the three SIC codes (2831, 2833, 2834). b) Other companies with substantial production in one or more of the three codes, but counting only those portions actually involved in that production.
2. Broad definition: a) Companies included under the restricted definition. b) Companies in which production in one or more of the three SIC codes is minor (or even nil) but which produce drug-related items such as cosmetics, toiletries, agricultural products, chemicals, hospital products, and nutritional products.

For a study of solid waste production, the number of physical locations producing waste is more important than the number of corporate entities involved. The existing ambiguity of definition, then, makes generalizations relating industry sales and employment statistics to specific solid waste para-

TABLE 1

GEOGRAPHICAL DISTRIBUTION
(From Dun and Bradstreet and Red Book data)

Number of Establishments in Region[a]

	A	B	C	D	E	F	G	H	I	Total
3 SIC[b]	105	712	189	387	57	128	192	32	257	2059
Unknown[c]	57	292	100	141	38	46	66	15	75	830
Total Drug[d]	162	1004	289	528	95	174	258	47	332	2889

Percent in Region

	A	B	C	D	E	F	G	H	I
3 SIC	5.1	34.6	9.2	18.8	2.8	6.2	9.3	1.5	12.5
Unknown	6.9	35.2	12.0	17.0	4.6	5.5	8.0	1.8	9.0
Total Drug	5.6	34.8	10.0	18.3	3.3	6.0	8.9	1.6	11.5

Percent in 5 Top States

	New York	California	New Jersey	Illinois	Pennsylvania
3 SIC	17.4	10.8	10.5	8.5	6.6
Unknown	21.7	7.7	6.5	6.4	7.0
Total Drug	18.7	9.9	9.4	7.9	6.7

a. Regions are defined as follows:
   A. New England
   B. Middle Atlantic
   C. South Atlantic
   D. East North Central
   E. East South Central
   F. West South Central
   G. West North Central
   H. Mountain
   I. Pacific

b. "3 SIC" refers to the establishments known to produce products in SIC codes 2831, 2833, or 2834.

c. "Unknown" refers to establishments listed as drug producers but whose SIC code is not known.

d. "Total drug" refers to all the establishments under notes b and c.

meters of interest highly unreliable.

Employment

According to the Pharmaceutical Manufacturers Association, industry employment in the United States totaled 125,500 in 1966, counting only prescription drug manufacturing.[5] Department of Labor estimates for 1966, including both prescription and proprietary manufacturing by companies classified in SIC code 283 (drugs), gave an employment figure of 127,000.[5] The 1967 Census of Manufactures gives a figure of 127,800 for companies whose primary products are characterized by the three SIC codes (up from the 1963 figure of 99,000).[6] The following table shows the 1967 Census breakdown:

	Number of Establishments	All Employees (1,000)	Total Payroll (million)	Production Workers (1,000)
SIC 2831	128	7.4	53.8	4.8
SIC 2833	126	8.4	67.1	5.6
SIC 2834	875	102.0	821.4	55.2
Total	1,129	127.8	942.3	65.6

Most companies listed by Dun and Bradstreet provided employment data, as follows[2]:

Region[a]	Total Number of Companies Listed	Number of Companies Supplying Data	Percent Supplying Data	Employment of Companies Supplying Data
A	107	92	85.9	6,042
B	721	624	86.5	482,333
C	191	169	88.4	16,109
D	397	328	82.6	199,232
E	60	44	73.3	5,781
F	129	105	81.3	7,783
G	193	164	84.9	15,547
H	32	27	84.3	722
I	267	215	80.5	61,939
Total	2,082	1,768	84.9	795,488

a. See p.viii.

Total Production and Plant Value for Industry

The drug industry consists of a group of about 30 "core companies" who in 1967 accounted for over 70 percent of prescription (and an even larger portion of proprietary) drug sales, with the remaining share of the market spread over about 2,000 smaller companies whose products, markets, and geographical areas of operation are generally specialized and restricted. The Census of Manufactures (1967) counts 1129 companies as primary producers in the three SIC codes, broken down as follows:

	No. of Companies
SIC 2831	128
SIC 2833	126
SIC 2834	875

This definition of the industry is even more limited than the restricted definition given above, and is not an accurate indication of size, especially for SIC codes 2831 and 2833.

Sales. It is difficult to find the convincing and consistent data necessary for an accurate evaluation of the financial size of the drug industry. Sales figures, for example, depend on which definition of the industry (restricted or broad) is used, as well as on inclusion or exclusion of foreign sales. Statistics for 1967, the last year for which reasonably complete figures are available, follow.

	1967 Sales	Percent of next higher category
All manufacturing corporations	$ 575.4 billion[7]	
Chemical and allied products	47.5 billion[7]	8.2
Pharmaceuticals*	8.3 billion[7]	17.4
Ethical drugs**	5.1 billion[8]	61.4
Domestic	3.6 billion[8]	
Foreign	1.5 billion[8]	

*Includes drug-related items as mentioned in the broad definition (p. 9).
** According to reference 8; however, "ethical drugs" here probably includes proprietary drugs (see Census figures, p. 13).

According to these figures, the broadly defined drug industry ("Pharmaceuticals") accounts for 1.4 percent of total 1967 sales for all manufacturing corporations. Under the restricted definition ("Ethical drugs"), the industry accounts for 0.88 percent of total sales.

Bureau of the Census statistics for 1967 give a total of $4.955 billion for value of product shipments in the three SIC codes. The lower figure (instead of $5.1 billion) can probably be accounted for by the Bureau's use of "net selling value" (i.e., not including discounts, allowances, and returns) as opposed to "list price." The Census figures are broken down as follows[6]:

SIC 2831	$ 221 million	(= 4.5% of total)
SIC 2833	594 million	(= 12.0% of total)
SIC 2834	4,140 million	(= 83.5% of total)
	$4,955 million	

These figures represent data for shipment of products in the three SIC codes by all industries. Companies specifically characterized as primarily engaged in production in the three SIC codes account for the following portions of these figures[6]:

	Primary Companies (Million)	Primary % of Total	Other Companies (Million)	Total (Million)
SIC 2831	$ 135	61	$ 86	$ 221
SIC 2833	333	56	261	594
SIC 2834	4,016	97	124	4,140

Dun and Bradstreet statistics current to November 1969 give sales volume figures by region for 1203 companies whose primary or secondary SIC codes are 2831, 2833, or 2834. These figures represent total sales volume, including all products, not only drugs or drug-related products. These statistics are:[2]

Region[a]	Total No. of Companies Listed	No. of Companies Supplying Data	Percent Supplying Data	Sales Volume of Companies Supplying Data
A	107	69	64.4	$ 72,698,900
B	721	368	51.0	11,491,611,040
C	191	121	63.3	307,263,311
D	397	237	59.6	5,674,542,700
E	60	42	70.0	171,498,100
F	129	94	72.8	186,490,700
G	193	107	55.4	256,306,700
H	32	18	56.2	3,456,500
I	267	147	55.0	2,513,232,810
Total	2,082	1,203	57.7	$20,677,100,761

a. See p. viii.

Net Worth. An approximate idea of the net worth of the industry can be derived from another set of Dun and Bradstreet statistics.[2] The relatively low percentage of companies represented indicates the difficulty of obtaining this kind of information, as well as the level of reliability that can be attributed to it.

Region[a]	Total No. of Companies Listed	No. of Companies Supplying Data	Percent Supplying Data	Net Worth of Companies Supplying Data
A	107	49	45.7	$ 15,944,490
B	721	226	31.3	5,200,113,723
C	191	98	51.3	123,063,680
D	397	164	41.3	3,229,936,587
E	60	41	68.3	87,961,216
F	129	68	52.7	108,308,650
G	193	71	36.7	114,082,083
H	32	18	56.2	2,406,860
I	267	83	31.0	567,589,640
Total	2,082	818	39.2	$9,449,406,929

a. See p. viii.

Summary

In summary, the bulk of the drug industry consists of over 2,000 companies, with 1967 drug sales of about $5 billion accounting for just under one percent of total sales by U.S. manufacturing corporations. The actual number of employees engaged in production of drug products is not determinable from available references but falls somewhere above the 1967 Census figure of 127,800 (which counts only companies whose primary production is in SIC codes 2831, 2833, and 2834). Information on net worth is too incomplete to provide a basis for valid generalization.

PRODUCTION PATTERNS

From an inconspicuous segment of the national economy before World War II, the American pharmaceutical industry has become a significant force in the complex structure of today's socio-economic fabric. The industry's dramatic growth in size and varieties of products is reflected in increased quantities and types of solid wastes which require modern approaches for handling and disposal.

Past. In the early decades of this century, to World War II, the drug industry consisted primarily of a large number of small companies, all producing a relatively small number of general-purpose medications and preparations. In 1914, 3,815 companies, employing 25,502 workers, made products classified as "druggists preparations." With some fluctuation between, the numbers by 1931 were 2,353 companies with 33,619 employees. An early trend toward concentration is evident. Statistics for companies whose products were classified as "biological products and pharmaceutical preparations" are available for years from 1929 on. The trend shows a relatively stable number of companies with steadily increasing employment. In 1929, 1,392 companies employed 35,460 persons; in 1958, 1230 companies employed 85,694 persons.[9]

Early products were a few natural drugs, some biologicals; mainly patent medicines and druggists' preparations, tinctures, fluid extracts, elixirs, and pills. Most of the growth in the industry to World War II resulted from increased production of specific chemicals (e.g., barbiturates, laxatives) and of vitamins. Over half of 1939 sales of $300 million was due to proprietary drugs.[10]

Waste disposal was not a matter of concern to the industry before World War II. A description given in 1945 by one industry official is probably typical:

> Up until 1945 waste collection was done by horse- and tractor-drawn wagons and disposal was accomplished by open-pit burning and burying. This method required 80 to 100 man hours per day and the almost constant use of a rented bulldozer to dig and cover pits.[11]

The foundations for present production patterns were laid between the years of World War II and about 1954. The large wartime military demand for blood plasma, vaccines, tablet and powder drugs, and the new antibiotic, penicillin, produced a rapid increase in size. The companies most affected were those that had the basic technology, experience, and equipment—i.e., the capability to expand rapidly into high-volume production—for the highest-priority products. Charles Pfizer Co., for example, became the world's largest penicillin manufacturer by 1945 because of its existing advanced fermentation technology when the demand arose.[10]

With the end of the war, the demand for many drugs slackened little, if at all; the market merely shifted from military to civilian channels. The central core of major producers created by the war still dominates the industry, though some tendency away from concentration has become evident in recent years.[12]

From 1945 to 1954, antibiotics and traditional products like vitamins, barbiturates, and laxatives accounted for most of the industry's growth. After 1954, the heavy research investment begun during the war and continued afterwards resulted in the introduction of the original "wonder drugs," the tranquilizers and steroids.[10] The industry's growing emphasis on development of new products since then has produced (and continues to produce) an impressive array of more specific and more effective products.

With the wartime increase in size came the industry's first recognition of waste disposal as a significant problem. The types of waste were essentially the same (filter sludge, fermentation media, biological wastes,

animal wastes, dust), but the quantities had reached proportions unheard of before. More recently, highly toxic and radioactive wastes have complicated the problems further. For solid wastes, the basic methods of disposal have changed little from the techniques first adopted in the late 1940's: hauling to a dump or landfill, incineration, sewering, burying. The most significant changes have involved

1) sanitary landfill disposal (i.e., wastes covered a minimum of once a day) instead of open burning
2) limited attempts to reclaim useful byproducts (e.g., composting)
3) government-regulated disposal of narcotic and radioactive wastes
4) on-site incineration in efficient, high-capacity industrial incinerators using supplementary fuel (e.g., natural gas)

Future. From the original pattern of producing general, all-purpose medications, mainly of the proprietary type, the industry has come to production of predominantly specialized drugs designed to be effective against a single condition or a limited range of conditions or to produce a single effect or a limited range of effects. Ethical drugs now dominate the market, accounting for about 70 percent of domestic sales.

No basic change appears likely in the types of products to be marketed. The initial wave of discoveries seems to be past, and new product are getting harder to find, though intensive research continues. Major emphasis will be placed on retaining or improving competitive positions in existing products. Normal expansion of demand will continue to increase quantities produced.

Competition from generic-name drugs (e.g., pentobarbital, the generic name for Nembutal) is still smal but is growing. If this becomes a major factor, companies with dominant shares of the market may lose ground to smaller companies.

Production patterns will be affected by mergers and diversification. Historically, most companies have concentrated their efforts in a fairly limited field, based on past experience or success or on analyses of future potentials.[10] Diversification into other product lines

(whether by expansion or acquisition of other companies) may stimulate wider interest within the drug field itself, so that a given company may produce a greater variety of drugs than it does now. Mergers may contribute to concentration or diffusion, depending on the nature of the companies. If they market substantially similar lines, production will tend to become concentrated in the new single company. If, however, their lines are substantially dissimilar (a more likely kind of merger in the face of governmental anti-trust interest), the new company's interests will be more diverse.

The lapse of a patent generally results in a substantial redistribution of the existing market pattern of a drug, as competition becomes significant. Drugs patented from 1954 on will lose protection beginning in 1971, so that significant changes in production patterns can be expected in this decade.

The effects of patent lapses will be mitigated somewhat by the rapidity with which many drugs are replaced by improved versions or newer drugs. With the decrease in new discoveries, however, existing drugs will tend to remain on the market longer, so that the overall effect is difficult to assess.

The single biggest impact on future production patterns is likely to be due to various forms of governmental activity. Government programs (Federal & State) for health care establish criteria for contents and quality, affecting production and quality control processes. Governmental power to approve or reject new drugs for marketing can be critical. Current emphasis on demonstrable efficacy, not just safety, has already had a significant impact and will have to be taken into account in all future applications. Accelerated review of new drug applications has been and can be used to encourage production of particularly desirable items. Anti-pollution legislation, in extreme cases, may force a given company to discontinue a product or process or to move to another location if the requirements of the law cannot be met. Strict pollution requirements will also affect production processes by encouraging salvage and recycling of wastes or usable byproducts. Investigation and possi-

bly legislation in the areas of price structures and of advertising and promotion may also encourage or discourage production of certain items, by affecting their profitability or marketability.

Barring unforeseen major breakthroughs in new drugs, the present period of consolidation will continue. Basically the same kinds of drugs will be produced in greater quantities to meet normally rising demand. Ethical drugs should maintain and probably increase their share of the market. The trend away from domination by a few companies should continue, producing a broader base for industry expansion. Solid waste production, consequently, should also increase substantially in quantity but retain the same basic character.

PRODUCTS AND PROCESSES

PRODUCTION PROCESSES

The pharmaceutical industry combines a wide variety of manufacturing methods. Among others, these include packaging, capsuling, fermentation, mixing, grinding, biological and botanical extractions, chemical synthesis, and tableting (Table 2). Other processes include bulk and individual sterilization, blending, and coating of tablets. A sizeable aerosol formulation is also included in manufacturing. All processes are conducted on scales varying from single small runs to those requiring huge continuous-run installations. Figures 2 through 10 indicate the points of solid waste generation for general production processes.

TABLE 2

MANUFACTURING PROCESSES REPORTED

Operation	Multiple SIC[a] (Total 7)	SIC 2833 (Total 5)	SIC 2834 (Total 17)
Packaging	7	0	17
Capsuling	4	0	8
Fermentation	5	1	2[b]
Mixing	7	3	17
Grinding	5	3	14
Extractions	7	5	3
Synthesis	5	3	4
Tableting	6	0	17
Other[c]	3	0	0

a. Companies characterized by production in more than one SIC code.

b. Used in production of non-drug (e.g., enzyme) products.

c. Not specified further to avoid possible company identification.

Since the drug industry also conducts extensive chemical, biological, and microbiological research, all of the waste products produced by such activities are present here. Some of these research products are found to be toxic in animal tests and present a special waste disposal problem.

The use of radioisotopes, both for research purposes and in marketed products, also presents its waste disposal problems.

In brief, then, the pharmaceutical industry presents solid waste management problems which combine those of the chemical, fermentation, and veterinary fields.

Products and Processes

SIC 2831 - Biological Products

Figure 2 is a diagrammatic representation of a typical production process for the manufacturing of biological products. Bacteria (certain actinomycetes) or fungi (penicillium) are inoculated as seed cultures in a chemical medium which is allowed to ferment for a designated time. After fermentation, the bacterial or fungal solids are extracted from the fermentation tank and either discarded as solid wastes or further extracted for product and, after this secondary extraction, discarded as solid wastes. Upon purification and weighing, the biological or chemical product is used in liquid or tablet preparations, depending on the manufacturer's product requirement.

SIC 2833 - Medicinal Chemicals

Figure 3 is a diagrammatic representation of a second typical production process portraying the manufacture of medicinal chemicals. Animal tissue is chemically extracted and purified and concentrated. Spent animal tis-

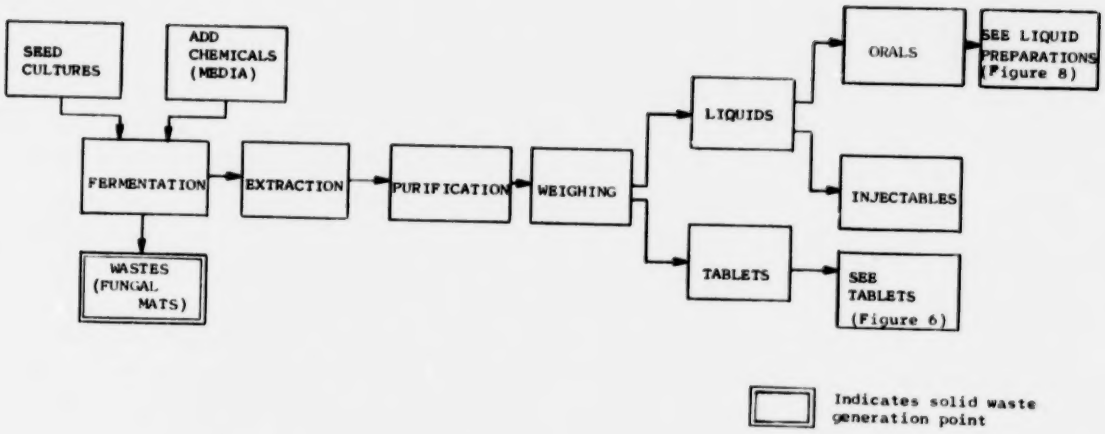


Figure 2. Production of Biologicals

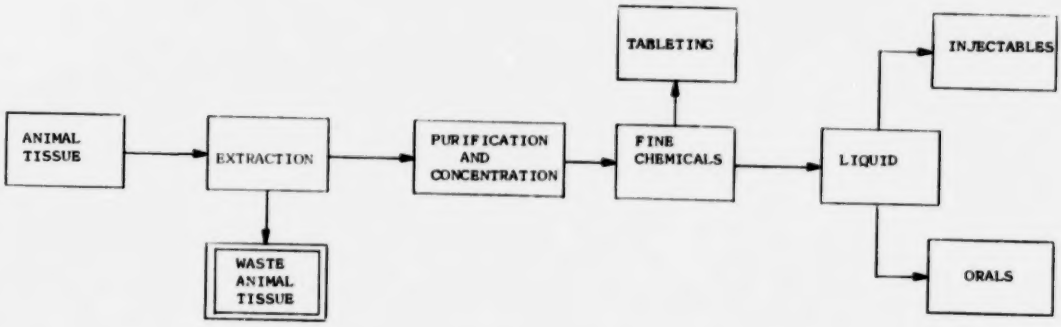


Figure 3. Production of Medicinal Chemicals

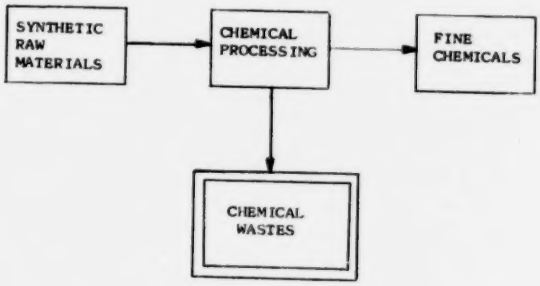


Figure 4. Production of Synthetic Medicinal Chemicals

sue is generated as a solid waste. Fine chemicals are the end product of the process. These chemicals are used in either tablet or liquid preparations.

The production of synthetic medicinal chemicals is depicted in Figure 4. Synthesis consists of the chemical processing of synthetic raw materials into fine chemicals. Chemical solid waste products result from this type of processing.

SIC 2833 - Botanical Products

Botanical products are manufactured by chemical extraction of botanical materials as seen in Figure 5. The extraction process yields considerable solid waste in the form of spent botanical materials such as bark, leaves, and dregs. Fine chemicals are produced after extraction by purification and concentration. Finished product is used in tablets or liquid preparations.

SIC 2834 - Pharmaceutical Preparations

Production of tablets is shown in Figure 6. Fine chemicals are weighed, followed by mixing which produces chemical dust as a solid waste. After mixing, granulation and tableting of the fine chemicals is accomplished. The tablets are either coated and bottled or bottled without coating, depending on the desired end product specifications. Samples of the tablets are sent to Quality Control (Q.C.) for analysis of the pharmaceutical prior to release to packaging. In the tableting and bottling phases, rejected product residues and waste pharmaceuticals from Q.C. arise as solid waste problems. Further solid wastes, either as packaging material or glass breakage, occur in the packaging of the bottled tablets.

Capsule production, Figure 7, is similar to the production of tablets. Fine chemicals are weighed and mixed (chemical dust occurs as solid waste). The

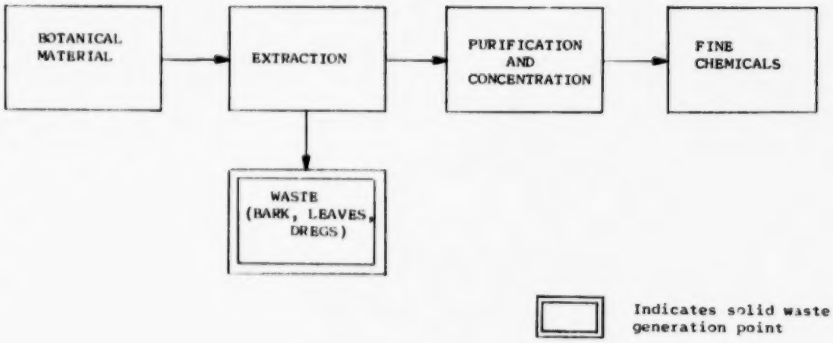


Figure 5. Production of Botanical Products

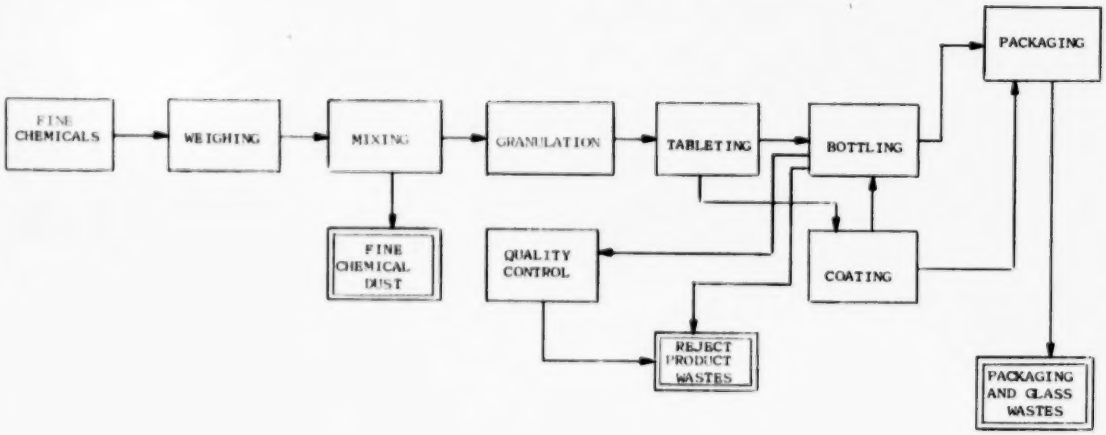


Figure 6. Production of Tablets

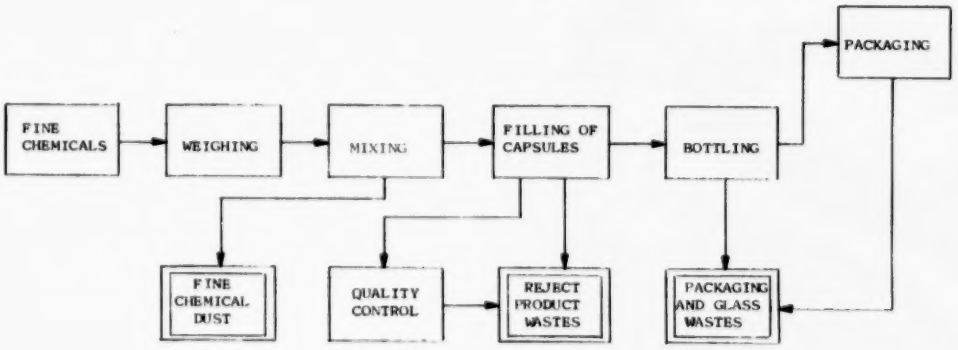


Figure 7. Production of Capsules

weighed and mixed fine chemicals are placed into capsules. Some of the drug-filled capsules are sent to Q.C. and some are rejected as defective. After Q.C. approves the batch of capsules, they are bottled and packaged, with further samples of the final package being returned to Q.C. for clearance. Some glass breakage occurs in the bottling and packaging, which results in solid wastes. Although Q.C. samples are retained for five to seven years, they also ultimately become waste.

Production of liquid preparations, as seen in Figure 8, begins with the mixing of fine chemicals and water. The resulting chemical solution is bottled as an oral product or is used in injectable products with appropriate sterilization and bottling. Solid wastes result from the Q.C., bottling, and packaging operations.

Salves or ointments are produced, as seen in Figure 9, by the mixing of fine chemicals and thickening agents. Packaging of the mixture of chemical and thickening agent results in solid wastes in the form of reject filled and unfilled metal tubes and jars and glass breakage.

Aerosols are produced by mixing fine chemicals propellants, such as freon, followed by cold or pressure filling of cans. Figure 10 depicts this production scheme. Solid wastes occur in the packaging process in the form of filled or unfilled waste cans, as well as in rejects from Q.C.

These nine production processes are typical of those practiced in the preparation of biological products, medicinal chemicals and botanical products, and pharmaceutical preparations throughout the drug industry.

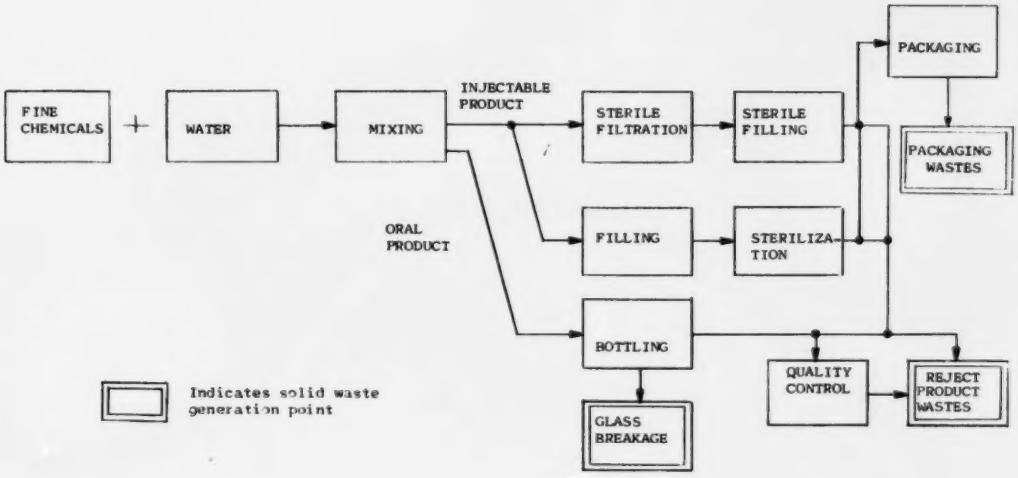


Figure 8. Production of Liquid Preparations

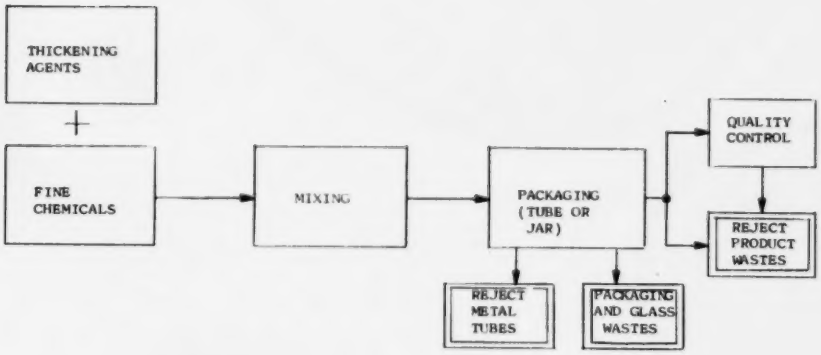


Figure 9. Production of Salves or Ointments

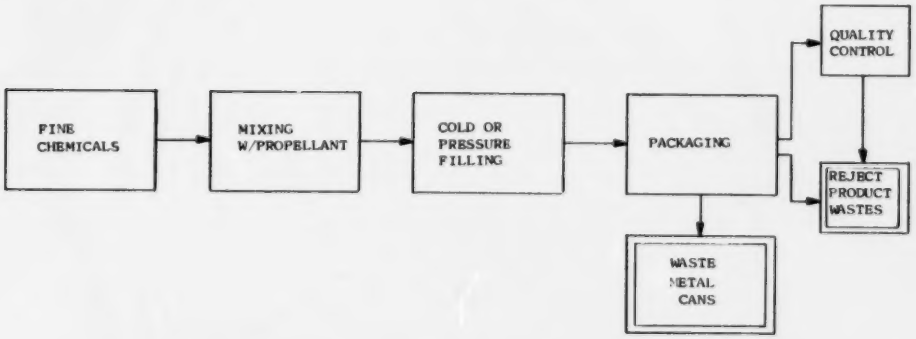


Figure 10. Production of Aerosols

PRODUCTS MARKETED

Numerous products are manufactured under the three SIC codes, 2831, 2833, 2834, included in this study. General categories with two example products under each SIC code are given below to depict the marketed products for the industry. A complete list of products marketed is found in the National Drug Code Directory[13] and the 1967 Census of Manufactures.

2831 Biological Products

Biological products for human use

Blood and blood derivatives for human use

Vaccines and antigens for human use

Biological preparations for veterinary use

Vaccines and viruses

Bacterins and mixed bacterins

2833 Medicinal Chemicals and Botanical Products

Synthetic organic medicinal chemicals in bulk

Antibiotics, in bulk

Other synthetic organic chemicals, in bulk

Other medicinal chemicals and botanical products, in bulk

Botanical drugs and derivatives, in bulk (uncompounded)

Naturally occurring vitamins (from yeast, plants, fish liver, etc.) in bulk

2834 Pharmaceutical Preparations

Pharmaceutical preparations affecting neoplasms, endocrine system and metabolic disease, for human use

Hormones and synthetic substitutes, total

Other pharmaceutical preparations affecting neoplasms, the endocrine system and metabolic diseases

Pharmaceutical preparations acting on the central nervous system and the sense organs, for human use

Internal analgesics and antipyretics

Psychotherapeutic agents

Pharmaceutical preparations acting on the cardiovascular system, for human use

- Anticoagulants
- Hemostatics

Pharmaceutical preparations acting on the respiratory system, for human use

- Antihistamines, except cold preparations and anti-emetics
- Bronchial dilators, including antiasthmatics

Pharmaceutical preparations, acting on the digestive or the genito-urinary systems, for human use

- Antidiarrheals
- Laxatives, total

Pharmaceutical preparations acting on the skin,for human use

- Dermatological preparations, total
- Rubbing alcohol

Vitamin, nutrient and hematinic preparations,for human use

- B complex preparations
- Fluoride preparations

Pharmaceutical preparations affecting parasitic and infective diseases, for human use

- Penicillins (single): injectable
- Antibiotics, general, oral

Pharmaceutical preparations for veterinary use

- Anesthetics
- Antibiotics

ANALYSIS OF DEVELOPMENT AND PRODUCTION PATTERNS

Since the pharmaceutical industry, with its emphasis on research, truly lives upon innovation and discovery, it is impossible to predict accurately what new solid wastes will be produced five years from now. However, there may be some clue from recent developments in the industry and projecting them.

There has been a distinct swing toward the dispensing of medicines in the hospital in unit dose form. Thus tablets and capsules are now packaged in foil, plastic laminates or paper strips, put up in cardboard boxes rather than bottles of 50, 100, or 1,000. The result of such a shift in the end product will increase the packaging materials portion of manufacturing waste, but will not change the composition or quantity of other production solid wastes. Unit dosage for injectable liquids takes the form of either disposable plastic syringes with attached single-use throwaway needles or cylinders made of glass or plastic sealed with synthetic plastic plugs which fit into a metal syringe. The net result is that 10 syringes or tubes are needed to replace a single 10-cc multiple-dose vial wherever such vials are used today. In the case where a sealed glass ampoule (single-dose container for standard hypodermics) is used today, such a replacement is approximately equivalent as a solid waste problem. From the manufacturing standpoint, aside from packaging,no appreciable change in solid waste production results from this trend. At present approximately 25 percent of the output of the pharmaceutical industry is utilized in hospitals. With expanding Medicare it is predicted that this will be substantially increased in the next decade.

Another trend which likely will continue is the substitution of plastic containers for glass to distribute tablets, capsules, and oral liquid preparations to the ultimate user. As a result, the consumer solid waste generation will change accordingly. At the manufacturing level only the waste generated in the packaging department will reflect such trends.

It is difficult to predict what kinds of new drugs will reach the market in the next decade. However, since the drugs which will be marketed within the next three to four years are now on trial in the clinic, it

is safe to predict that no great changes in manufacturing and processing will appear. The basic fermentation and chemical syntheses, while differing in end product, will, for the most part, produce the same types and amounts of solid waste as are generated today. This is, of course, subject to a continuing overall growth of the industry as a whole.

In summary, except for the shift of multiple to single unit packaging in the hospital side of the pharmaceutical business of the future, it is expected that the generation of solid wastes in this industry will be of the same type and amount relative to the total sales volume.

METHODS AND PROCEDURES

METHOD OF SAMPLE SELECTION

Nine geographical regions of the United States (as described on page viii) were used to initially locate the drug companies for the intended interview survey. These regions are used by the U.S. Department of Commerce in defining manufacturers and SIC code products. Further company selection was made in Regions B, D, G (Missouri only) and I (except Alaska and Hawaii). This is based on the knowledge that the main bulk of the drug companies in the three SIC codes are located in these four regions (12 states).

Employee number, as defined in Table 3, was the criterion in dividing the establishments into small, medium, and large for further sample selection. Geographical clustering was avoided. If a large plant produced all three SIC product categories, this was considered as fulfilling a visit to three individual facilities. Therefore, although interviews were conducted at 29 plant locations, production in more than one SIC code at some of these results in an effective total of 37 producers with each SIC code tabulated separately. Because of lack of detail in reported employment figures, total employment number was used to determine size for production in each SIC code. As a result, the size categories for a given SIC code indicate the size of the total plant operation, not just that part of it devoted to that SIC code. For example, a plant with total employment of 1010, producing in all three SIC codes, would appear under SIC 2831 - Large, SIC 2833 - Medium, and SIC 2834 - Medium.

At the beginning of the interview effort, it was intended to visit establishments such that an even distribution according to SIC code and size would be achieved, as shown in the tabulated breakdown on page 34.

TABLE 3

DISTRIBUTION OF DRUG COMPANY FACILITIES BY EMPLOYMENT AND MAJOR REGIONS

	NUMBER[a] OF FACILITIES BY REGION[b]							
	Region B	Region D	Region G	Region I	TOTAL (4 regions)	Range of Employee Number	% of Facilities in Specified SIC Code	Number of Facilities Interviewed
SIC 2831								
S[c]	31	15	3	6	55	0-300	82	0
M[c]	3	2	1	1	7	301-1,000	10.5	1
L[c]	2	3	0	0	5	1,001+	7.5	3
SIC 2833								
S	104	30	5	20	159	0-300	82	5
M	14	6	1	5	26	301-1,020	13.4	1
L	6	2	1	0	9	1,021+	4.6	3
SIC 2834								
S	379	126	37	78	620	0-100	80.5	3
M	66	31	5	21	123	101-1,499	16	16
L	18	7	2	0	27	1,500+	3.5	5
Total	623	222	55	131	1,031			37

a. Only facilities for which employment figures are available are tabulated.

b. B - New Jersey, New York, Pennsylvania
D - Ohio, Indiana, Illinois, Michigan, Wisconsin
G - Missouri
I - California, Oregon, Washington

c. S - Small; M - Medium; L - Large

	Establishments		
	Small	Medium	Large
SIC 2831	(0-300) [a]	(301-1000)	(1001 +)
(Biological Products)	2	2	2
SIC 2833 (Medicinal Chemicals & Botanical Products)	(0-300) 2	(301-1020) 2	(1020 +) 2
SIC 2834 (Pharmaceutical Preparations)	(0-100) 5	(101-1499) 5	(1500 +) 5

a. Number of employees defining size

A number of factors contributed to the differences between the original plan and the actual distribution at the end of the effort. Among the more significant are the following:

1. Agreement of contacted firms to cooperate. Reluctance of some companies was due to sensitivity to a Federal government study and to fear of adverse publicity (despite assurances of anonymity).
2. Definition of size as discussed on page 32. If total employment figures for each plant could be broken into fractions devoted to each SIC code, a more nearly even distribution would result.
3. Travel for interview purposes was confined to certain areas by financial and time considerations. The types of plants physically accessible therefore became a limiting factor.
4. Relatively limited number of plants producing only in SIC 2831 or 2833. Most companies in these SIC codes overlap with SIC 2834. This fact, combined with factors 1, 2, and 3, prevented contact with a small SIC 2831 plant.

On the whole, the 29-plant sample appears to be fairly representative of the drug industry, within the limitations imposed by the small size of the sample. Total employment at the surveyed facilities ranged from 5 to

6000; reported annual sales volumes for 1969 ranged from less than $1 million to over $50 million; and their geographical distribution corresponds generally with the areas containing the largest concentrations of pharmaceutical manufacturers.

TYPE OF QUESTIONNAIRE

Since the study was conducted by personal interviews, the questionnaire (see Appendix C) was used as an interview guide. The questionnaire consisted of fifteen parts for the description of production and solid waste management practices of a pharmaceutical plant. For clarification of the meaning of the three SIC code groups, an introductory page defining them was included. A pretest phase of the questionnaire was initiated prior to final approval by U.S. Bureau of the Budget (BOB). In this phase, one establishment in each SIC code was visited with the questionnaire. Their suggestions provided important help in finalizing the BOB-approved version of the questionnaire.

INTERVIEW FORMAT

The procedure of contacting and interviewing an establishment was the following:

a. The consultant contacted the plant to ask if they would be willing to be surveyed.
b. Upon agreement of a plant, an approved field questionnaire was sent to the appropriate person (as determined by the consultant) in the plant.
c. The plant was then visited and the appropriate persons interviewed. The information obtained was verified by a walk through the facility.
d. At the end of the interview an attempt was made to see the executive who allowed us into the plant and explain our findings to him.
e. The information was assimilated after the visit and telephone contact for missing information was made if required. The collected information was then compiled into a report (case history) summarizing and describing the pharmaceutical plant's solid waste management practices.
f. A copy of the case history was sent to the person who had been interviewed for verification of the recorded data.

RELIABILITY OF INFORMATION

Actual quantities of solid wastes generated by the 29 interviewed pharmaceutical plants were estimates by plant managers and engineers, directors of operations, and vice-presidents of manufacturing. Generally, experimental animals and their wastes and radioactive wastes can be considered reliable. Only one pharmaceutical plant had actually measured its solid waste load; all others estimated their waste quantities. The cost of solid waste management given by most plants probably is unreliable, since most plants do not keep extensive records concerning the labor and equipment costs involved in solid waste management.

All plants gave reliable information concerning the general description of the plant facility with reference to employment, location, and plant processes. Tabulation of sources and description of solid waste materials for all plants is considered accurate. Description of disposal methods and the frequency of waste collection is reliable. Each plant practicing salvage was very cooperative in discussing this operation; therefore, information on this aspect is reliable.

In conclusion the descriptive (qualitative) portions of the information obtained can be considered reasonably accurate; however, the quantitative sections concerning solid waste quantities and solid waste management costs are of questionable and variable reliability. Consequently, the data obtained are poorly suited to meaningful statistical analysis.

DATA ANALYSIS AND PRESENTATION

GENERAL

The data presented in this section are based on company responses to the questionnaire developed for this study (Appendix C). As a rule, the response rate was excellent (Table 4). On twelve of the fifteen sections in the questionnaire, the rate of replies to applicable questions was over 90 percent; two were over 80 percent. The low response rate (51 percent) on Part XIII (Salvage or Re-use) is due partly to some ambiguity in question structure and partly to difficulty in the concept of economic or geographic limitations affecting salvage or re-use of wastes.

Figure 11 is the flow diagram of solid wastes in the drug industry. Originating with materials which are utilized in production processes, the solid wastes then arise during these production processes. These wastes are then handled and disposed of by various methods. Package fabrication accounts for the most common and frequently occurring materials and wastes (paper, glass, metal,and plastic). The remaining production processes contribute the more sophisticated wastes (reject pharmaceuticals, fermentation cake, chemicals, spent animal tissue and organs, etc.). Nothing is unique in the handling of these process wastes, and the methods of solid waste disposal are similar to municipal solid waste disposal practices (incineration, land disposal, and composting).

Summation of the solid waste quantities arising from production processes, and the costs associated with the handling and disposal of these wastes are shown in Table 5. The numbers in this table were calculated in the following manner. Total employment at the plant site and total waste load (pounds/day) (columns 3 and 4) were taken from the plant's case history as was the annual expenditure for waste management (column 7). The waste load per employee (column 5) was calculated by dividing column 4 (total waste load) by column 3 (employment number). Annual waste load (column 6) was based on the knowledge of the waste load per day or per month. Daily or monthly figures were multiplied by either 260 days/year (52 weeks x 5 days/

TABLE 4

FREQUENCY OF QUESTIONNAIRE RESPONSES[a]

Part	Question	Reply[b]	No Reply	Not Applicable[c]	Part	Question	Reply	No Reply	Not Applicable
I	1	29	0	0	X		7[d]		1[e]
	2a	29	0	0		1	18	3	0
	2b	29	0	0		2	20	1	0
	2c	29	0	0		3	11	10	0
		100%				4	20	1	0
II	1	29	0	0		5	21	0	0
	2	26	3	0		6	21	0	0
	3a	28	1	0		7	16	5	0
	3b	26	3	0		8	20	1	0
	4	24	5	0		9	21	0	0
		91.7%				10	20	1	0
III	1	29	0	0			92.1%		
	2	29	0	0	XI				23[e]
	3	29	0	0		1	6	0	0
	4	28	1	0		2	6	0	0
		99.1%				3	5	1	0
IV		29	0	0		4	6	0	0
		100%				5	4	2	0
V		29	0	0		6a	5	1	0
		100%				6b	2	4	0
VI		29	0	0		7	4	2	0
		100%				8	5	1	0
VII	1a	29	0	0			81.6%		
	1b	29	0	0	XII				26[e]
	2a	28	1	0		1	3	0	0
	2b	25	4	0		2	3	0	0
	3	29	0	0		3	3	0	0
	4a	29	0	0		4	3	0	0
	4b	29	0	0		5	3	0	0
	5a	26	3	0		6	0	3	0
	5b	26	3	0			83.3%		
	5	27	2	0	XIII	1a	29	0	0
		95.5%				1b	19	10	0
VIII	1	29	0	0		2a	8	0	21
	2a	6	0	23		2b	6	10	13
	2b	3	3	23		3	4	12	13
	2c	6	0	23		4a	10	19	0
	3	28	1	0		4b	1	19	9
	4a	8	1	20			51.0%		
	4b	0	1	28	XIV	1	29	0	0
	5	29	0	0		2	29	0	0
	6	28	1	0		3	29	0	0
		95.1%				4	29	0	0
IX	1	29	0	0			100%		
	2	15	0	14	XV		29	0	0
	3a	15	0	14			100%		
	3b	15	0	14					
	3c	15	0	14					
		100%							

a. See Appendix C for copy of questionnaire.
b. An indication of "None" or "Not applicable" is considered to be a reply, as is an incomplete answer.
c. "Not Applicable"refers only to questions which do not require an answer if a previous question is answered in a particular way (e.g., questions 2a, 2b, 2c in Part VIII are applicable only if the answer to question 1 is "Yes").
d. These seven answers indicate "no knowledge" for all information in Part X (characteristics of land disposal site).
e. When the method of disposal covered in Part X, XI, or XII is not used, the company is counted under "Not Applicable" whether an actual response was made or not.

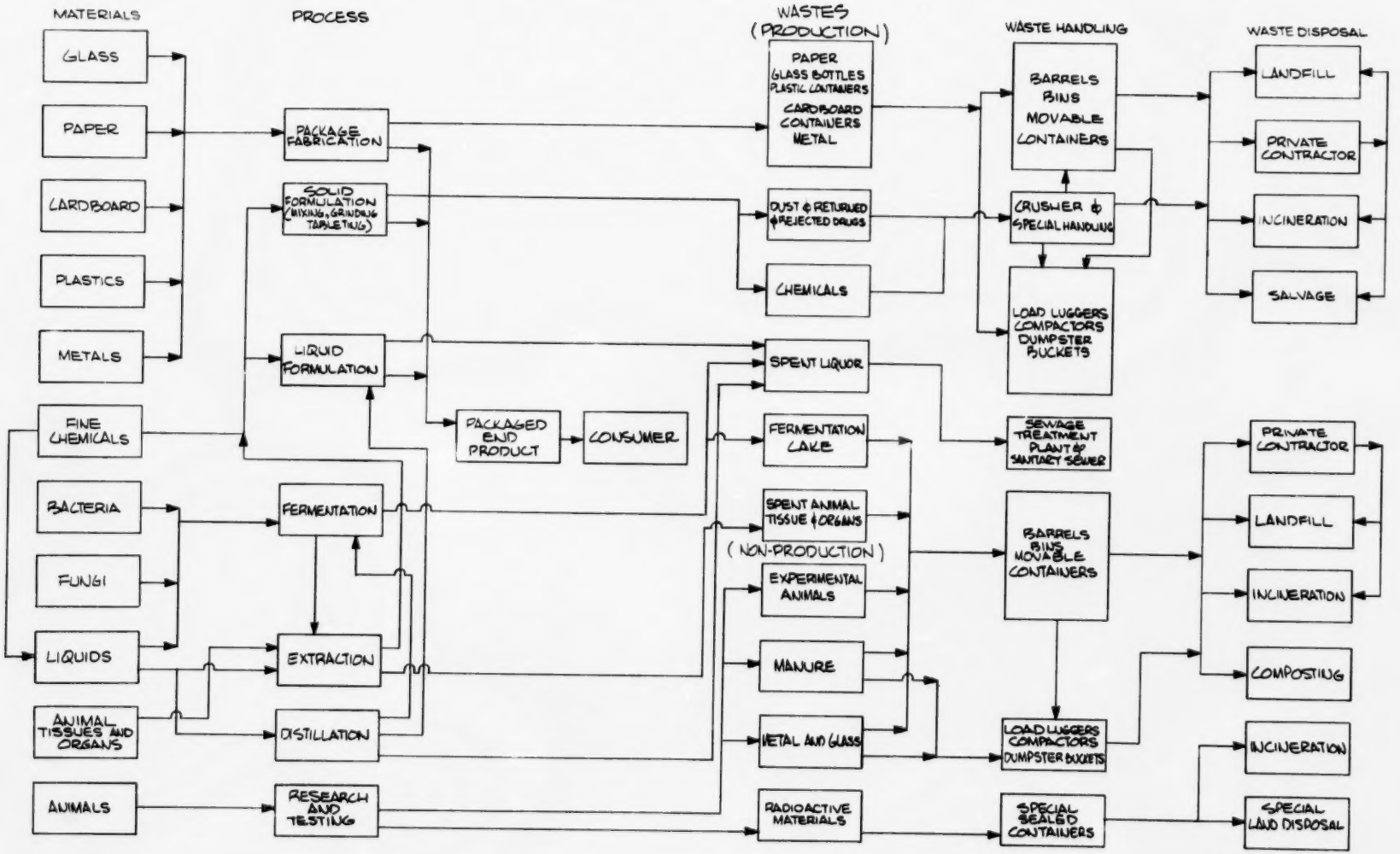


Figure 11

Flow Diagram of Solid Wastes in the Drug Industry

TABLE 5. SUMMATION OF SOLID WASTE QUANTITIES AND MANAGEMENT COSTS

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
									COST OF SOLID WASTE MANAGEMENT $/YEAR					WASTE DISPOSAL $/TON		
INTERVIEW NUMBER	SIC CODE	EMPLOYEES AT PLANT SITE	TOTAL WASTE LOAD pounds per day	WASTE LOAD PER EMPLOYEE pounds per day/per employee	ANNUAL WASTE LOAD tons per year	ANNUAL EXPENDITURE FOR WASTE	COST PER TON	POINT OF ORIGIN	INTERMEDIATE POINTS	PRETREATMENT	HAUL TO FINAL DISP	IN HOUSE DISPOSAL	OFF SITE DISPOSAL	ON SITE INCINERATION	ON SITE LANDFILL	HAUL AWAY
1	2833 2834	475	11,160[a]	20.3	1,450	125,000	86.20	50,000			75,000					52.19
2	2831 2834	800	24,000[a]	30.0	3,120	35,000	11.21	8,750	7,000		14,000	5,250		5.05		6.70
3	2834	300	52[b]	0.17[b]	6.76[b]	Cost figures not available.										
4	2834	489	2,038	4.16	265	103,000	388.67	61,800		10,300	20,600	10,300		101.52		80.83
5	2834	214	5,800	27.1	754	10,400	13.67	1,040			9,300	60				12.70
6	2833	283	14,300	50.5	1,860	39,000	20.96	10,920			19,500	780	7,800			10.50
7	2833	269	61,550	222.9	8,004	51,500	6.45	11,200			25,750		14,550			3.28
8	2833	30	155[a]	5.2	20	5,000	250.00	500				4,500		56.25	168.75	
9	2831 2834	3,500	146,690	41.91	19,070	82,000	4.30				49,200	32,800				
10	2831 2834	1,250	7,105	5.68	929.5	23,000	24.67	2,300			15,700	5,000		16.00		17.50
11	2834	1,800	17,625	9.8	2,291.25	295,000	128.75	10,000	250,000		30,000	5,000		128.20		13.32
12	2833 2834	6,000	95,077	15.85	12,360	300,000	16.18		50,000	20,000	105,000	25,000		18.60		9.53
13	2833	5	46	9.2	6	2,700	450.00				2,700					450.00
14	2833	60	2,200	36.7	286	8,580	30.00				8,580					30.00
15	2834	298	1,710[c]	5.74	222.3	21,000	94.46			3,150	8,400	9,450		72.00		92.30

a. Average figure.
b. Not including mixed production wastes.
c. Before change in disposal of wood pallets. New figure is 1210 lb/day.

TABLE 5. SUMMATION OF SOLID WASTE QUANTITIES AND MANAGEMENT COSTS (continued)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
									COST OF SOLID WASTE MANAGEMENT $/YEAR					WASTE DISPOSAL $/TON		
INDUSTRY NUMBER	SIC CODE	EMPLOYEES AT PLANT SITE	TOTAL WASTE LOAD pounds per day	WASTE LOAD PER EMPLOYEE pounds per day/per employee	ANNUAL WASTE LOAD tons per year	ANNUAL EXPENDITURE FOR WASTE	COST PER TON	INVEST. OF CRUSH.	INDEPENDENT POINTS	BY DEPARTMENT	HAUL TO FINAL DISP.	IN HOUSE DISPOSAL	OFF SITE DISPOSAL	ON SITE INCINERATION	ON SITE LANDFILL	HAUL AWAY
15	2843	1,500	32,100	21.4	4,170	58,000	13.90				58,000					13.90
	2844															
17	2834	133	371	2.80	48.5	12,000	247.42	8,000		2,000	2,000					41.25
18	2834	119	160	1.3	20.8	6,120	294.23	612			5,408					260
19	2834	140	570	4.07	74.1	6,000	80.97	2,400	2,400		1,200					16.19
20	2834	62	138	2.22	18	4,000	222.22	2,400			1,600					88.88
21	2834	177	3,760	21.3	480	9,600	19.63	2,400			4,800	2,400		36.19		11.20
22	2834	36	750	20.83	97.5	1,000	10.25				1,000					10.25
23	2834	755	37,750	50.00	4,907	74,500	15.18	7,450	63,325		3,725					0.76
24	2834	314	1,030	4.77	132.6	8,600	64.85		3,612		1,290	3,698		33.01		57.07
	2831															16.15
25	2833	5,846	153,969	26.34	20,022	98,000	4.89	65,660			32,340					
	2834															
26	2834	1,400	37,077	26.48	4,820	71,500	14.83	42,000	750	750	12,000	16,000		22.96		2.91
27	2834	736	80,468	109.33	10,464	37,000	3.53	3,700		1,850	7,400	9,250	14,800			0.71
28	2834	600	23,347	38.91	3,035	32,000	10.54	15,040			12,800	4,160				4.26
29	2834	80	180	0.0	23.4	1,770	75.64	1,345			425					18.16

week) or 12 months/year, respectively, and converted to tons of waste/year if the figure was in pounds. To obtain the cost/ton of waste management (column 8), annual cost (column 7) was divided by annual waste load (column 6).

Cost of solid waste management is divided into six categories: collection at point of origin; collection at intermediate points; haul to final disposition or treatment; pretreatment; in-house disposal or treatment; and off-plant-site disposal or treatment. Percentages of solid waste management costs in each of these categories were given in the case histories. These percentages were used to calculate the part of the total annual waste management cost attributable to each category. An example is Interview No. 4 which had an annual expenditure of $103,000. Sixty percent ($61,800) was spent for point of origin collection; 20 percent ($20,600) for hauling costs; and 10 percent ($10,300) each for pretreatment and in-house disposal costs.

Dollars per ton of waste (columns 15-17) is used to explain the cost of the method of solid waste disposal practiced by the interviewed companies. These figures were calculated knowing the total percentage of the waste disposal method, the annual waste load, and the cost of disposal. Interview No. 6, for example had 100 percent of its solid waste hauled from its premises. The plant's annual waste load was 1,860 tons/year; the company paid $19,500 to have the waste hauled from the plant site. Dividing $19,500 by 1,860 tons/year yields $10.50/ton of hauled solid waste for company cost. Because of limitations in the provided figures, it was not possible to break out every method of disposal used by each company. The amounts calculated for hauling cost per ton (column 17) must also be considered rough approximations, since most include off-site disposal costs as well as actual transportation costs. Furthermore, costs per ton (columns 15-17) differ from column 8 due to the different techniques used in disposing of the wastes. (Certain tons of waste are incinerated on-site while other wastes are hauled from the site.)

SOLID WASTES

Sources

Table 6 summarizes the number of reports of specific source materials which make up the solid wastes from both production and non-production activities in the three SIC codes and in other products. (The possible total of 60 reports results from the fact that most plants are represented under two or more of the five categories.) The figures, though basically reliable, must be considered approximate to some degree because of uncertainty introduced by the necessary reliance on memory by the persons interviewed. Since no in-depth surveys of waste production were made, some items were undoubtedly overlooked.

No surprising data emerge from these figures. The solid waste categories most common to other industries--paper, plastic, wood, glass, and metal--rank highest here also. The other major item is returned and rejected products, including waste chemicals from production, which appear in all three SIC codes. The industry's considerable research and development effort is reflected in the high incidence of experimental animal remains under the nonproduction category. The indefinite nature of some of the waste material description terms results from answers on the questionnaire which could not be made more specific (i.e., cafeteria wastes, production solids).

Types and Quantities

Tables 7 and 8 show the breakdown of quantities and types (as defined in the questionnaire) of waste produced in SIC codes 2833 and 2834. Interviews with plants producing in more than one SIC code are not included in the tabulation, since quantities could not be broken out into separate figures for products in each code. SIC code 2831 is omitted because no company interviewed produced only biological products as defined under that code. Wastes not included in one of the other categories are listed under the "Undifferentiated Miscellaneous" column. The figures in these tables, of course, include both production and nonproduction activities.

TABLE 6
FREQUENCY OF REPORTED SOLID WASTE TYPES

	Production			Other Products (2 reports)	Non-Production (21 reports)	Total (60 reports)
	SIC 2831 (4 reports)	SIC 2833 (9 reports)	SIC 2834 (24 reports)			
Paper	2	6	21	2	14	45
Cardboard	1	1	13	2	2	19
Plastic	2	2	19	1	5	29
Wood	0	1	12	0	4	17
Rubber	0	0	1	0	0	1
Glass	1	3	19	1	3	27
Metal	0	2	11	0	8	21
Dust	0	0	10	1	0	11
Waste Chemicals Rejects and Returns	2	3	22	1	4	32
Spent Biological Tissue	2	1	0	0	0	3
Spent Botanicals	0	4	0	1	0	5
Animal Remains	2	0	3	0	12	17
Manure	0	0	0	0	9	9
Bedding	1	0	1	0	6	8
Radioactive Waste	0	0	1	0	5	6
Ashes	1	0	0	0	1	2
Filter Cake	0	7	0	1	0	8
Fermentation Solids	1	1	0	1	0	3
Acid Wastes	0	1	0	0	0	1
Sewage Sludge	0	0	0	1	1	2
Garbage	0	0	0	0	7	7
Cafeteria Wastes	0	0	2	0	2	4
Fatty Materials	0	1	0	0	0	1
Rags	0	0	0	0	1	1
Mixed production wastes (misc.)	0	4	0	0	0	4
Production Solids (undifferentiated)	0	0	1	0	0	1
Construction (rubble)	0	0	0	0	1	1

TABLE 7

POUNDS PER DAY - SIC 2833

INTERVIEW NUMBER	EMPLOYEES	GARBAGE	MIXED PRODUCTION WASTES	ASHES	STREET REFUSE	ANIMAL REMAINS	PRODUCTION PROCESS WASTES	SEWAGE SOLIDS	MANURES	UNDEFF. MISC.	TOTAL
6	283 (170)[a]		924 (6.5)[b]				13,481 (93.5)				14,404
7	269 (216)		15,411 (25.0)				46,140 (75.0)				61,551
8	90 (30)		100 (64.5)	5 (3.2)			50 (32.3)				155
13	5 (5)						41.4[c] (100)				41.4
14	60 (60)		200 (9.1)				2,000 (90.9)				2,200

a. Production employees are given in parentheses (Tables 7 and 8).
b. Percent of total is given in parentheses (Tables 7 and 8). These may not total 100 because of independent rounding.
c. Average figure.

TABLE 8

POUNDS PER DAY - SIC 2834

INTERVIEW NUMBER	EMPLOYEES	GARBAGE	MIXED PRODUCTION WASTES	ASHES	STREET REFUSE	ANIMAL REMAINS	PRODUCTION PROCESS WASTES	SEWAGE SOLIDS	MANURES	UNDEFF. MISC.	TOTAL
4	480 (192)	150 (7.4)	1,600[a] (78.5)	10 (0.5)		28 (1.8)			200 (9.8)		2,038
9	214 (150)		5,700 (98.3)						100 (1.7)		5,800
11	1,800 (325)	500 (2.8)	16,000 (90.8)			800 (1.7)	800 (4.5)			25[b] (0.2)	17,625
17	133 (75)	100 (26.8)	115 (30.8)	4 (1.1)			4 (1.1)			150[c] (40.2)	373
18	119 (32)		150 (93.8)			5 (3.1)	5 (3.1)				160
19	140 (77)	20 (3.5)	500 (87.7)				50 (8.8)				570
20	62 (23)	92.3 (66.7)					46.1 (33.3)				138.4
21	177 (126)	100 (2.7)	500 (13.3)	50 (1.3)		10 (0.2)	3,000 (79.8)		100 (2.7)		3,760
22	36 (17)		600 (80.0)				150 (20.0)				750
23	755 (450)	100 (0.3)	36,400 (96.4)		20 (0.1)		1,230 (3.2)				37,750
24	214 (51)	10 (1.0)	750 (73.5)	100 (9.8)	10 (1.0)		150 (14.7)				1,020
26	1,400 (308)	---4,800 (13.1)---		500 (1.3)		500 (1.3)	17,216 (46.4)		14,000 (37.8)	1[b]	37,077
27	736 (582)		11,090 (14.9)				49,971 (62.1)	18,507 (23.0)			80,468
28	600 (150)	3,000 (12.8)	7,500 (32.1)		600 (2.6)	240 (1.0)	9,600 (41.1)		2,400 (10.3)	-[b]	23,347
29	30 (18)		180[a] (100)								180

a. Combination of various waste types including process wastes.
b. Radioactive wastes.
c. Rejects and returned drugs.

Without insisting too heavily on the absolute accuracy of these quantities, it is clear that mixed production wastes and production process wastes provide the great bulk of the solid waste load. These are defined in the questionnaire as follows:

Rubbish (= mixed production wastes): Containers, cartons; plastics; wood; excelsior; bedding; tin cans; glass; crockery; scrap metals; labels and other waste materials; rags; miscellaneous office wastes; vending machine wastes.

Production (Process) Wastes: Waste biologic material; eggs; discarded microbial masses; waste drug materials; dusts; diatomaceous earth and fillers; waste solid chemicals; etc.

The lack of garbage, street refuse, and sewage solids in SIC 2833 can probably be attributed to the small size of the plants or to incompleteness in answering the questionnaire. The absence of animal remains and manures is attributable to the nature of the product (medicinal chemicals and botanical products). Research and testing with animals is not significant in this field since the products are primarily raw or intermediate-stage materials to be processed later into products for ultimate use by consumers and the medical profession.

COMPARISON OF WASTE GENERATION WITH EMPLOYMENT

Surprisingly, Table 9 shows little relationship between total solid waste production and either total employment or number of production employees. Not counting the anomalous (and incomplete) figure for Interview No. 3, the waste load per total employment varies between 1.3 and 222.9 pounds per day; and waste load per production employee ranges from 5 to 284.9 pounds per day.

A general idea of "reasonable" numbers for large establishments can be

TABLE 9

COMPARISON OF TOTAL SOLID WASTE GENERATED WITH EMPLOYMENT

Interview	Employees	Production Employees	Total Waste Load (pounds/day)	Waste Load Per Total Employment	Waste Load Per Production Employee
1	475	275 (= 57.8%)	11,160	20.3	40.6
2	800	370 (= 46.2%)	24,000	30.0	64.9
3	300	125 (= 41.6%)	52[a]	0.17	0.4
4	489	192 (= 39.2%)	2,038	4.2	10.6
5	214	150 (= 70.0%)	5,800	27.1	38.7
6	283	170 (= 60.0%)	14,300	50.5	84.1
7	269	216 (= 80.2%)	61,550	222.9	284.9
8	30	30 (= 100.0%)	155	5.2	5.2
9	3500	1580 (= 45.1%)	146,690	41.9	92.8
10	1250		7,105	5.7	
11	1800	325 (= 18.0%)	17,625	9.8	54.2
12	6000		95,077	15.9	
13	5	5 (= 100.0%)	46	9.2	9.2
14	60	60 (= 100.0%)	2,200	36.7	36.7
15	298	216 (= 72.4%)	1,710 (1210)[b]	5.7 (4.1)	7.9 (5.6)
16	1500	729 (= 48.6%)	32,100	21.4	43.9
17	133	75 (= 56.3%)	373	2.8	5.0
18	119	32 (= 26.8%)	160	1.3	5.0
19	140	77 (= 55.0%)	570	4.1	7.4
20	62	23 (= 37.0%)	138	2.22	6.0
21	177	126 (= 71.1%)	3,760	21.2	29.8
22	36	17 (= 47.2%)	750	20.8	44.1
23	755	450 (= 59.6%)	37,750	50.0	83.9
24	214	51 (= 23.8%)	1,020	4.8	20.0
25	5846	2556[c] (= 43.7%)	153,969	26.3	60.2
26	1400	398[c] (= 28.4%)	37,077	26.5	93.2
27	736	582 (= 79.0%)	80,468	109.3	138.3
28	600	150[c] (= 25.0%)	23,347	38.9	155.6
29	30	18 (= 60.0%)	180	6.0	10.0

a. Mixed production wastes.

b. Recent change from disposal to selling of wood pallets gives the lower figures in parentheses.

c. Includes production control employees.

deduced from data for the five largest companies (by total employment) for which complete figures are available:

Interview	Total Employment	Production Employees	Waste Load Per Total Employment (lb/day)	Waste Load Per Production Employee (lb/day)
9	3,500	1,580	41.9	92.8
11	1,800	325	9.8	54.2
16	1,500	729	21.4	43.9
25	5,846	2,556	26.3	60.2
26	1,400	398	26.5	93.2

Dividing total employment for these five large companies (14,046) into total waste load from Table 9 (387,461 lb/day) gives an average of 27.6 lb/day per employee. (Adding the figures for Interview 12 from Table 9 decreases the average to 24.1.) Dividing the number of production employees (5,588) into the total waste load for the five companies gives an average of 69.3 lb/day per production employee.

Since employment alone, however, is not consistently reliable as a parameter to correlate with waste load, a better criterion must be established. It is likely that no single "universal parameter" will suffice for this purpose. The most promising approach, based on interviewing experience, appears to be the determination of waste load by production processes used (e.g., fermentation, extractions, synthesis, grinding). Development of this parameter into a useful criterion, however, would require definitive quantitative studies conducted at a number of representative plant sites. Such knowledge of processes and volumes of materials processed, perhaps in combination with such data as employment or sales volume, is likely to provide highly accurate correlations for analysis of present and future solid waste loads from the industry.

SOLID WASTE MANAGEMENT

Analysis of Collection and Disposal Systems

Practices. Table 9A summarizes the methods of solid waste disposal at the 29 interviewed pharmaceutical plants. The most frequent method of disposal was hauling from premises to a privately or publicly owned disposal site. Incineration was the second most frequent method of disposal. The numbers representing the frequency of method of disposal indicate the number of facilities using this disposal method. However, more than one waste handling method may be used by the same plant. For example, 15 plants have their garbage hauled from their premises while 3 manufacturing sites incinerate their garbage. However, the 3 plants incinerating may also use haul-away as a secondary waste removal method. This also explains why the haul-away type of collection varies in number for self-haul and private collection. Since the same company may itself haul some waste to the disposal site in conjunction with contracting to a private collector to haul away other segments of the waste, the numbers appearing in the columns under "hauled by" will not be additive to equal "hauled from premises" figures. Therefore, using garbage again as an example, the 15 plants having wastes hauled away - 14 by private collector and 4 by themselves - is to be interpreted as 3 plant sites handling some of their wastes by themselves while the remainder of their wastes is hauled by a private collector.

Another conclusion that can be drawn from Table 9A is that experimental animal remains are generally incinerated. However, after incineration the ashes are generally hauled away by either the plant itself or a private collector. There are cases where the animal remains are not incinerated but are removed by a private collector.

In cases where the solid waste left the pharmaceutical plant via private contractor, the off-site disposal method was not investigated. In this

Table 9A

METHODS OF SOLID WASTE DISPOSAL

AT 29 PHARMACEUTICAL PLANTS

TYPE OF WASTE	METHODS OF DISPOSAL					HAULED BY		
	Land Fill	Spread on Land	Incineration	Hauled from Premises	Composting	Self	Private Collector	Public Collector
Garbage	-	-	3	15	-	4	14	-
Mixed Production Waste	-	-	6	18	-	10	15	-
Ashes	1	-	-	11	-	2	11	-
Street Refuse	1	1	-	9	-	2	9	-
Experimental Animal Remains	-	-	10	2	-	5	4	-
Production Process Wastes	1	1	3	20	1	10	15	-
Sewage Solids	-	1	-	-	1	3	-	-
Manures	-	-	1	8	1	3	7	-

study it was the intention to report on all on-site plant solid waste handling and disposal techniques. The adequacys of off-site disposal methods, where a private collector would deposit a pharmaceutical plant's wastes, was not a subject of this study since it was felt to be out of the scope of the project.

Barrels, bins, and movable containers were used in handling most solid wastes. These containers were taken to an area where they were dumped into a dumpster bucket, compactor, or load lugger employed for accumulation of the waste materials. Periodic removal, from several times a day to twice a week, occurred from this waste accumulation point. At 75.9 percent of the interviewed plants, part or all of the wastes were removed by contract haulers; 41.3 percent of the interviewed plants hauled some or all wastes themselves (17.2 percent used both contractor services and their own hauling resources). Land disposal sites (privately and publicly owned and operated) were the most prevalent method of disposal for wastes hauled from the plants. However, 51.7 percent of the interviewed plants performed some type of incineration on their own sites.

Pretreatment of wastes was performed by 58.6 percent of the plants, while 34.4 percent sorted solid wastes prior to haul-away or disposal. Returned or reject drugs and company labels were the most common items pretreated prior to disposal. These wastes were crushed in a hammermill device for complete defacing and demolishing. The end product of the crusher was then wetted down with water to prevent identification of certain drugs and pharmaceuticals in the remains. The crusher remains were then hauled from the plant for land disposal or were incinerated. Plants which did not follow the crushing procedure usually had the rejects and labels buried at a land disposal site under supervision of a plant employee. Incineration without crushing also was used to dispose of labels and rejects.

Solid materials in suspensions generally were flushed down the drain into the municipal sewage system, although 28.6 percent of the pharma-

ceutical plants practiced solid-liquid separation by use of a sedimentation basin. Radioactive wastes, generated from research activities, were usually placed in special containers and handled and disposed of by an AEC licensed disposal firm in the area. Some plants were licensed to incinerate their radioactive wastes. Experimental animal remains from research were customarily incinerated in a pathological incinerator, while other plants froze the remains and had them removed for burial or off-site incineration.

The most abundant and everyday solid wastes (paper, cardboard, glass, metal, and wood) were common to approximately all plants and were handled in barrels, bins, and movable containers and accumulated and disposed of as described above. Some plants (27.6 percent) salvaged a portion of their solid wastes. Cardboard was the main salvaged item. Some plants were able to salvage fermentation solids and sell them as byproducts. However, this byproduct operation was conducted at large pharmaceutical plants only. One facility composted about two-thirds of its solid wastes, producing a usable soil conditioner and fertilizer which was given to employees and used on the plant grounds.

Basically, the pharmaceutical industry uses the same handling and disposal equipment and techniques common to the handling and disposing of municipal solid wastes. These are barrels, bins, compactors, dumpster boxes, and land disposal and incineration. Some plants prefer to follow the philosophy "Out of sight - Out of mind" in that their solid wastes are hauled from the plant site for ultimate disposal. Other plants, however, are concerned enough to accompany the solid waste to the disposal site.

Safety precautions taken in handling especially hazardous or toxic chemical wastes generally involved standard industrial safety practices specified for labeling, handling, and segregated storage. Specific practices of interest were:

a. Bury in cement and haul away
b. Store in small-volume safety cans

c. Convert liquids to solids for safer handling and storage
d. Detoxify or neutralize before disposal
e. Incinerate
f. Submerge reactive chemicals in alcohol

Economics. The lack of detailed and accurate records which became evident during the course of this study indicates that costs associated with solid waste management are usually lumped into a general "miscellaneous" category. With rare exceptions, they are merely part of the cost of doing business, not a separate economic category to be reckoned with on an individual basis. In particular, no attempt seems to have been made before by the industry to break the waste management process into its component practices (pretreatment, collection at point of origin or intermediate points, in-house disposal, haul to final disposition, etc.) for analysis of costs and efficiency.

On the basis of this study, it appears that the single largest expense for most companies is the cost of hauling waste to final disposition (Table 5, p.41-42). Several companies, however, indicated that collection at point of origin or at intermediate points accounts for the largest single expense. Little significance can be attached to these distinctions, however, because of a probable lack of common understanding as to the meanings of the categories in the questionnaire. This lack of consistency did not become evident until the final compilation and comparisons of statistics.

Even the undifferentiated totals for quantities of waste and for annual waste management expenditures show no reasonable pattern of relationships. Gross annual costs ranged from $1,000 to $295,000, but only a very erratic relationship exists between these figures and the quantities of wastes involved. Thus the combined statistic of annual cost per ton shows a wide spread of values, ranging from $3.53 to $450.00. Dividing the total annual cost for 28 companies (one did not release cost figures) by their total annual waste load gives a mean annual cost of $14.36 per ton for total solid waste management.

Some additional relative cost indications can be derived from figures for waste management costs as related to employment (Table 10). Interestingly, the companies whose production is characterized by more than one SIC code show a significantly lower average annual cost per employee ($32.05) and per production employee ($72.23) than the companies producing in only one SIC code. For production in medicinal chemicals and botanical products (SIC 2833), these costs are $165.03 and $221.99, respectively; for production in pharmaceutical preparations (SIC 2834) they are $96.27 and $240.62, respectively.

In terms of size, the average annual cost per employee corresponds with average employment: Multiple SIC establishments, with average employment of 2,767, are lowest with $32.05; SIC 2834, average employment of 450, next with $96.27; SIC 2833, average employment of 129, highest with $165.03. The same pattern does not hold for annual cost per production employee, primarily because production employees comprise almost 75 percent of total employment in SIC 2833 establishments, but only 40 and 45 percent in SIC 2834 and Multiple SIC, respectively. A rough inverse relationship between number of employees and these costs is evident within SIC 2833 and Multiple SIC categories, but SIC 2834 shows no such trend.

Comparison of solid waste management practices by geographical regions (Table 11) shows that $17.89 per ton is spent on solid waste management in Region B (13 plants) as compared with $8.12 per ton spent in Region D (7 plants). Corresponding solid waste management cost data for other geographical regions have no significant value since the number of pharmaceutical plants sampled was not sufficient to draw any conclusions.

The reason for the higher cost in Region B is that those sampled pharmaceutical plants utilized fermentation and extraction manufacturing processes, as contrasted to Region D where primarily pharmaceutical preparation plants were interviewed. Fermentation and extraction processes produce more solid wastes and cost more to operate than a pharmaceutical preparations operation. In addition, land disposal is generally more expensive in Region B because of higher hauling and dumping costs re-

TABLE 10

WASTE MANAGEMENT COSTS AND EMPLOYMENT

Interview	Employees	No. of Production Employees	Annual Cost	Annual Cost per Employee	Annual Cost per Production Employee	Treatment and Disposal Methods[a]
			Multiple SIC[b]			
1	475	275	$125,000	$263.15	$454.54	H2, H1, I
2	800	370	35,000	43.75	94.59	H2, I
9	3,500	1,580	82,000	23.42	51.89	H1, C, I
10	1,250	---	23,000	18.40		H2, I
12	6,000	---	200,000	33.33		H2, I
16	1,500	729	58,000	38.66	79.56	H2
25	5,846	2,556[c]	98,000	16.76	38.34	H1, H2
Total	19,371	5,510[d]	398,000[d] 621,000	Avg. $32.05	Avg. $72.23[d]	
			SIC 2833			
6	283	170	$ 39,000	$137.80	$229.41	H1, I
7	269	216	51,500	191.44	238.42	H1
8	30	30	5,000	166.67	166.67	H1, I
13	5	5	2,700	540.00	540.00	H2
14	60	60	8,580	143.00	143.00	H1
Total	647	481	$106,780	Avg. $165.03	Avg. $221.99	
			SIC 2834[e]			
4	489	192	$103,000	$210.63	$536.45	H2, I
5	214	150	10,400	48.59	69.33	H2
11	1,800	325	295,000	163.88	907.69	H2, I
15	298	216	21,000	70.46	97.22	H2, I, H1
17	133	75	12,000	90.22	160.00	H2, I
18	119	32	6,120	51.42	191.25	H2
19	140	77	6,000	42.85	77.92	H2
20	62	23	4,000	64.51	173.91	H2
21	177	126	9,600	54.23	76.19	H2, I
22	35	17	1,000	27.77	58.82	H2
23	755	450	74,500	98.67	165.55	H2, H1
24	214	51[c]	8,600	40.18	168.62	I, H1, H2
26	1,400	398[c]	71,500	51.07	179.64	I, H2
27	736	582[c]	37,000	50.27	63.57	H1
28	600	150[c]	32,000	53.33	213.33	H2, I
29	30	18	1,770	59.00	98.33	H2
Total	7,203	2,882	$693,490	Avg. $96.27	Avg. $240.62	

a. H1 = hauled by plant resources; H2 = hauled by contractor; I = on-site incineration; C = composting. Presented in order of decreasing amounts of waste.
b. Plants characterized by production in more than one SIC code.
c. Includes production control employees.
d. Excluding Interviews 10 and 12.
e. Excluding Interview 3, for which no cost figures are available.

TABLE 11

WASTE MANAGEMENT COSTS BY GEOGRAPHICAL REGION

Interview	SIC Code	Total Waste Load (Tons/yr)	Annual Cost
	Region B (Middle Atlantic)		
4	2834	265	$103,000
5	2834	754	10,400
6	2833	1,860	39,000
7	2833	8,004	51,500
8	2833	20	5,000
9	2831 2834	19,070	82,000
10	2831 2834	929.5	23,000
11	2834	2,291.25	295,000
12	2833 2834	12,360	200,000
13	2833	6	2,700
14	2833	286	8,580
15	2834	222.3	21,000
16	2833 2834	4,176	58,000
Total		50,244	$899,180
	Region D (East North Central)		
17	2834	48.5	12,000
18	2834	20.8	6,120
19	2834	74.1	6,000
20	2834	18	4,000
21	2834	489	9,600
25	2831 2833 2834	20,022	98,000
26	2834	4,820	71,500
Total		25,492.4	$207,220

sulting from scarcity of available sites and stricter governmental regulation of waste disposal practices.

The wide disparities in cost figures shown in this study result, then, from lack of adequate records and from lack of consistency in definition

of waste management practices. In the aggregate, however, it seems clear that almost every company interviewed could reduce its waste disposal costs substantially with a thoroughly planned and integrated system making maximum use of modern, compatible items of equipment for transportation and treatment of solid wastes.

Aesthetics. Two factors are of prime importance in the aesthetic aspect of waste handling in the drug industry: the corporate image in the public eye and the strict requirements for cleanliness in the manufacture of pharmaceutical products. Since most facilities are in, or within one mile of, residential areas, the physical impact of the plant is an important part of corporate public relations. The relatively unfavorable publicity of recent years, though based on grounds other than environmental ones, has made the industry very sensitive to its corporate image and thus highly responsive to local public opinion. Plants using composting processes, for example, make every effort to prevent an unsightly appearance and obnoxious odors.

The corporate image and governmental requirements for cleanliness of operation combine to produce a generally tidy on-site waste handling procedure. Personal observation at the interviewed plants confirmed that points of waste accumulation were kept clean, incinerator residues were adequately controlled, and salvage of waste (mainly cardboard) was neatly done. At some plants there were limited but noticeable odors from fermentation operations and from extraction processes involving animal tissues and organs.

Future. The following table summarizes the responses to questions concerning expected developments in solid waste management over the next five years. Basically, the answers indicate that the industry generally expects increased quantities of the same types of waste, requiring little or no revision of management practices but costing more to treat and dispose of. Even the new types anticipated in two answers were new only to the companies involved, not to the industry. Expected revisions of practices consisted primarily of introduction of compaction and incineration, with two plants indicating plans to begin or increase recovery of wastes. Inflationary psychology is evident in expectations of cost increases, since most answers cited "general economic factors" as the

reason. A tabulated summary of the responses follows.

EXPECTED FUTURE DEVELOPMENTS

Parameter	No. of Responses	Percent of Total (29)
Waste Quantity		
Increase	17	59
Decrease	3	10
Remain same	9	31
	29	
New Types of Waste		
Yes	2	7
No	27	93
	29	
Revised Practices		
Yes	9	31
No	20	69
	29	
Costs		
Increase	24	83
Decrease	1	3
Remain same	4	14
	29	

Present Recycling Possibilities

Historically, recycling of waste has been the exception rather than the rule, since most companies found it more expedient and more economical to throw solid waste products away than to salvage them. With some limited exceptions, there is little indication of planned change either in the literature or in the results of this survey. Even in the advanced

treatment process of the new Eli Lilly plant at Clinton, Indiana (see page 72), the only solid waste recycling consists of recovery of mycelia from spent fermentation broth, to be sold as high-protein animal feed supplement. All other solid wastes are incinerated or oxidized to ashes, which are buried.

Eight of twenty-nine companies surveyed practice some form of salvage or recycling of solid wastes. The most common practices are baling of cardboard packaging for eventual reuse, and return of drums and containers to suppliers. Wooden pallets are also commonly returned to transporters or suppliers, but companies do not usually consider them solid wastes unless they become damaged enough to discard. One of the companies surveyed reclaims fermentation wastes for use as animal feed supplement, and one company composts waste to produce a soil conditioner and fertilizer. Several companies spread waste on land, but the emphasis is generally on disposal, not on usefulness to the soil. One company investigated the possibility of salvaging diatomaceous earth but found it to be uneconomical.

The growing emphasis on recycling of wastes as a weapon against pollution may force a change in the historical patterns of disposal in the drug industry. The most likely prospects for the future appear to be wider adoption of reclamation methods described above. Other possibilities include:

1. Recycling of glass and metal containers (bottles and cans) rejected or damaged before being filled with product
2. Biological treatment of extracted botanical dregs to create usable byproducts
3. Possible regeneration and reuse of filter materials

The hard fact is that at present the reclamation of waste is essentially a public service activity (which costs money) rather than an economic asset. Even the limited practice of composting has proved, in trials

at municipal solid waste composting plants and in the experience of one interviewed plant, to be at best a marginal activity because of limited marketability of the end product. Until economically more rewarding uses are found for reclaimed solid wastes to justify treatment costs, little voluntary progress can be expected in this area.

Involvement of Governmental Agencies

Each plant was asked whether any government agency was involved in its solid waste management practices, either in a regulatory capacity or in a coordinating capacity for long-range planning. About a third of the respondents indicated no regulatory activity (excluding the Food and Drug Administration). Those producing narcotics or using radioactive materials come, of course, under the jurisdiction of the Bureau of Narcotics and Dangerous Drugs and of the Atomic Energy Commission. Just under a third of the plants are affected by state and local ordinances, including air pollution requirements, health regulations, requirements for identification of wastes hauled to land disposal, and regulations on hauling and dumping fees.

Over half of the answers indicated no inclusion of their solid wastes in long-range planning by a planning agency at any level. As might be expected, some relationship with size exists: of the ten largest plants (employment from 736 to 6,000), six are included in planning at local, county, state, or regional levels; of the ten smallest plants (employment from 5 to 177), only two are included (one at local and one at state level).

The following table gives the breakdown of governmental involvement by agency and level. The percentages do not add up to 100 percent, since there is some overlap of answers due to involvement by more than one agency for some companies.

GOVERNMENT AGENCY INVOLVEMENT IN WASTE MANAGEMENT

Agency	No. of Plants (out of 29)	Percent
Planning		
Local	8	28
County	2	7
State	4	14
Regional	2	7
None	16	55
Regulatory		
AEC	9	31
Narcotics Bureau	6	21
State & local ordinances*	9	31
None	10	34

*Includes supervision by Air Pollution Control Districts or Health Departments.

Influence on Surrounding Communities

All but two of the interviewed plants are located in or within a mile of a residential area; the others are no farther than five miles away from one. In terms of solid waste production and management, however, most plants have very limited impact on adjacent communities. Four aspects are of possible significance:

a. Air pollution from incineration of solid wastes
b. Water pollution from landfill, dump, or spread-on-land disposal
c. Odors from composting or storage
d. Reduction of municipal land disposal capacity where a plant contributes a large volume of waste

Of these, the first three are less immediate than the last, since plants large enough to cause problems take care to avoid practices

that would result in poor community relations. The problem of shrinking land disposal capacity is a real one, on the other hand, and deserves further study. But it encompasses all industrial solid wastes, not just those of the drug industry, and must therefore be studied as a separate problem on a larger scale. Within its scope, this study revealed no actual case where solid waste disposal caused difficulties in the relationship between an interviewed plant and its surrounding communities.

CONCLUSIONS

The following conclusions can be drawn from the data gathered in this study:

1. The drug industry represents approximately one percent of the total sales volume by all U.S. manufacturing corporations. Figures on number of establishments (about 2,000) and employment (roughly 130,000 or more) are difficult to determine, because of variability in definition of relevant parameters. Net worth of the industry is essentially unascertainable because of company reluctance to release such information. Geographically, drug company facilities can be found in nearly all the states, but the bulk of the industry is concentrated in the Middle Atlantic, East North Central, and Pacific regions.

2. The types of products made and present manufacturing processes will probably remain basically unchanged for the next five years. Consequently, the industry does not expect future developments to result in new types of solid wastes, but quantities of existing types are expected to increase. Specifically, a trend toward unit dose packaging will add to the generated industrial solid waste load (as well as to municipal waste loads generated by consumers). If this expectation of larger waste quantities proves accurate, whatever present difficulties exist will be aggravated, and regulatory requirements now in force will be more difficult to conform with. The magnitude, but not the nature, of the problem will change. Some of the companies interviewed indicated plans to begin or expand compaction or to incinerate more waste. These methods are, of course, designed to reduce the physical volume of waste and seem to be steps in the right direction.

3. In general, the wastes generated at the interviewed companies consist of the types found in municipal refuse, plus production wastes and some special wastes resulting from research activities. Mixed

production wastes (such as containers, plastic and metal scrap, labels, and miscellaneous wastes) and production process wastes (such as fermentation solids, chemical dust, biological and botanical wastes) comprise the bulk of the waste load, with garbage (primarily from cafeteria activities) adding significant amounts at plants producing pharmaceutical preparations. Special and hazardous (toxic, corrosive, radioactive) wastes characteristic of research activities also occur primarily in pharmaceutical preparations activities.

4. Other than on a very gross scale, there appears to be little relationship between the number of employees and the amount of waste they generate. Based on the data from the six largest companies, the calculated average waste load per total employment is 24.1 pounds per day, and waste load per production employee (based on five large companies) is 69.3 pounds per day. However, from wide discrepancies in individual figures (ranging from 1.3 to 223 pounds per day per employee), it becomes clear that a more significant parameter to account for waste quantities must be established. Specific standard production processes, perhaps in conjunction with other determinable parameters, appear most likely to be amenable to correlation with the major types of wastes (production process wastes and mixed wastes). In-depth analysis of actual production would be the best way to gather such information.

5. Present disposal practices consist mainly of hauling solid wastes to land disposal sites off the plant's premises and of incineration for on-site disposal. About three-fourths of the interviewed plants have some or all of their wastes removed by contract haulers, although about 40 percent also haul part or all of their own wastes from the plant site. Incineration in some form is also practiced at about half of the plants. Most plants know how their waste is handled and disposed of after being hauled from the premises. Of the facilities involved, 75 percent showed at least some knowledge concerning the ultimate land disposal site; 25 percent indicated no knowledge at all.

6. On-site waste handling takes the form of pretreatment (58.6 percent of plants), sorting (34.4 percent), and solid-liquid separation (28.6 percent). Pretreatment consists essentially of wetting and crushing waste drugs. Most establishments indicated that no change in waste handling had taken place in the year before the interview and that no changes were anticipated in the next five years. The present techniques, then, are apparently satisfactory from their standpoint; and there seem to be no great pressures for change, either internal (economics) or external (environmental interests).

7. Little attempt is being made to salvage solid wastes for reuse or for byproduct production (although 27.6 percent of interviewed plants have some salvage operations). The present limited practice of baling cardboard boxes and packaging materials could easily be adopted more widely. The feasibility of salvaging glass and metal from damaged or defective bottles and cans before they are filled with product also warrants investigation. The reclamation of the great bulk of waste, however, awaits innovative and imaginative developments to make reclamation and byproduct creation economically feasible in smaller plant operations.

8. The accuracy of figures on costs of waste management is open to question, but some general estimates of cost levels can be derived. The single largest expense for most plants is the cost of hauling waste to final disposition, but several indicated that collection at point of origin or at intermediate points accounts for the largest single expense. Available data from 28 interviews yield a mean annual cost of $14.36 per ton for all aspects of solid waste management. Individual annual figures range from $3.53 to $450.00 per ton. Calculation of waste management costs per employee indicates that plants producing in more than one SIC code experience sig-

nificantly lower average annual costs for waste management than those producing in only one SIC code. A similar contrast in costs appears for establishments in different geographical regions, with the average annual cost in the Middle Atlantic States ($17.89 per ton) being over twice the cost in the East North Central States ($8.12 per ton). Relationships between costs and either quantity of waste or employment size are rough and erratic at best and allow no significant conclusion.

9. Solid waste management is generally not a distinct category of activity for which plants keep accurate records as to either expenses or volumes of generated wastes. The resultant need to rely on "educated guesses" for these figures seriously impairs the usefulness of many of the statistics compiled for this report. To assure accuracy of quantitative data, on-site detailed studies of actual waste flow, including classification and weighing, are required. On the financial side, certain management costs should be definable which can be extracted or derived from plant records (e.g., contract hauling fees, dumping fees, salaries of appropriate personnel, incinerator operating costs), to give reasonable estimates of the actual outlays for solid waste management.

10. Aesthetic aspects of waste handling at the interviewed plants are governed primarily by the corporate image in the public eye and by strict requirements, both inherent and regulatory, for cleanliness in plant operations. Personal observation revealed no significant aesthetic problems at points of waste accumulation and incineration or during waste handling and salvage operations.

11. There is some indication that a large plant (as measured by employment) is more likely to have its solid waste management practices regulated or supervised by some level of government than a small one. However, less than half of the plants indicated any awareness of comprehensive governmental planning which includes their solid waste.

In view of conclusion 4, regulatory agencies may well be advised to consider the adoption of parameters more significant to the generation of industrial solid wastes than employee number. The proper parameters, of course, are yet to be determined.

12. Although all but two of the interviewed plants are located in or within one mile of a residential area, their impact on the surrounding communities is primarily limited to accelerated reduction of local land disposal capacities by contributions of large volumes of solid wastes. Other possible effects, such as air pollution from incineration of wastes, water pollution from landfill or spread-on-land disposal, and odors from composting or storage, were not found to have significant impact.

13. Any impetus for change in waste generation, treatment, or disposal will have to come from outside the industry. This investigation has found little indication of internal pressures for change; on the contrary, an inflationary psychology prevails, with general acceptance and expectation of higher future costs for the same types of treatment and disposal methods.

REFERENCES

1. U. S. Bureau of the Budget. Standard industrial classification manual. Prepared by the Office of Statistical Standards. Washington, U.S. Government Printing Office, 1967. 615 p.

2. Dun's market identifier. New York, Dun & Bradstreet, Inc., Nov. 1969.

3. Cousins, Walter, ed. Drug topics red book 1969. New York, Topics Publishing Co., Inc., 1968. 584 p.

4. Cousins, Walter, ed. Drug topics red book, cumulative supplement no. 2, May 1969. New York, Topics Publishing Co., Inc., 1969. 128 p.

5. Pharmaceutical Manufacturers Association. Prescription drug industry fact book. 3d ed. Washington, 1968. 76 p.

6. U.S. Bureau of the Census, Census of Manufactures, 1967. Drugs. Industry Series: MC67(2)-28C. Washington, U.S. Government Printing Office, 1970. 35 p.

7. Where chemicals stand in changing economy. Chemical Week, 102(17): 28-33, Apr. 1968.

8. Ethical drug operations. Drug and Cosmetic Industry, 104:52-53, 149, Jan. 1969

9. Kalish, J. The drug industry - 1914-1964. Drug and Cosmetic Industry, 95:719-720, Nov. 1964.

10. Silberman, E.C. Drugs: the pace is getting furious. Fortune, 61:138, May 1960.

11. Arbogast, C.C. Incineration of wastes from large pharmaceutical establishments. In Proceedings; 4th Industrial Waste Conference, Purdue University, 1945. p. 225-259.

12. U.S. Department of Health, Education, and Welfare. The drug makers and the drug distributors. Prepared by the Task Force on Prescription Drugs, December 1968. Washington, U.S. Government Printing Office, 1968. 86 p.

13. U.S. Department of Health, Education, and Welfare. National drug code directory. Prepared by Science Information Facility, Food and Drug Administration, October 1969. Washington, U. S. Government Printing Office, 1969. 347 p.

APPENDIX A

SUMMARY OF DRUG INDUSTRY SOLID WASTE MANAGEMENT LITERATURE

APPENDIX A

SUMMARY OF SOLID WASTE MANAGEMENT LITERATURE

In 1945 C.H.P. Arbogast of Lederle published in the Proceedings of the 4th Industrial Waste Conference, Purdue University, an article entitled "Incineration of Wastes from Large Pharmaceutical Establishments." Lederle's plant site at Pearl River, New York, is described with respect to size and employment. A general description of the types of solid wastes generated in conjunction with specific quantities of certain wastes (manures, sewage sludge, waste powders, broken glass, rubbish, and contaminated solvents) shows the solid waste handling problem at that time. Lederle had decided in 1945 to install an incinerator manufactured by Nichols Engineering & Research Corporation of New York. The article gives a detailed description of this incinerator.

The same year, E.L. Knoedler and S.H. Babcock, Jr., of Lederle wrote a report for Industrial and Engineering Chemistry, May 1945, entitled "Pharmaceutical and Biological Plants - Industrial Wastes." A detailed description of both the solid and liquid wastes is given.

Mortimer A. Clift of Nichols Engineering and Research Corp. contributed to Sewage Works Engineering, January 1948, an article called "Incinerating Wastes from a Large Pharmaceutical Establishment." This paper is a further detailed description of the incinerator described in Arbogast's paper three years earlier. A mechanical engineering discussion of the incinerator along with actual pounds of solid wastes incinerated are contained in this article.

"Biological and Pharmaceutical Wastes" by Carl G. Mauriello of Lederle was published in the Industrial Wastes Operation section of Sewage and Industrial Wastes in November 1958. There is a brief description of the treatment facilities, operation, odors, and control of concentrated waste at Lederle. A. J. Gabaccia, Head of the Industrial Waste Department of Lederle, presented before the Federation of Sewage and Industrial Wastes Associations annual meeting in October 1958 a paper, "Organic Sludge Composting Practice at Lederle." This paper, retitled "Composting

Waste Sludge From Pharmaceutical Manufacturing," was published in Sewage & Industrial Waste, October 1959. It discusses the composting of solid wastes (manures, sewage sludge, and sawdust) at Lederle. The biological process Lederle developed and patented is described in conjunction with the Earp-Thomas Digester that Lederle attempted to use in treatment of their solid wastes. The Earp-Thomas method was not amenable to the pharmaceutical company's solid wastes. Chemical oxygen demand (COD) was used as a parameter to monitor the composting process. An extension of this work was published by J.H. Friedman in Compost Science, Autumn 1963, entitled "Safe Disposal of Waste Solids."

A more up-to-date explanation of Lederle's capabilities of handling liquid and solid wastes is contained in A.H. Molof's article "Pharmaceutical Waste Treatment by the Trickling Filter, Activated Sludge, and Compost Processes," published in Biotechnology and Bioengineering, 1962. The wastewater treatment facilities are described in this paper.

Finally, an extensive and up-to-date description of Lederle's solid waste management practices is contained in a paper by D.G. Reihard presented at the Tenth Sanitary Engineering Conference, under the subject classification Waste Disposal from Water and Wastewater Treatment Processes, given at the University of Illinois in 1968. The paper is entitled "Recovery of Usable Waste Products," and the main theme is the past and present composting at Lederle.

An article by T.W. Bloodgood entitled "Treatment of Animal Wastes at the Greenfield Laboratories of Eli Lilly & Company" was published in the Proceedings of the 21st Industrial Waste Conference, Purdue University, 1966. The author describes the waste treatment plants at the Greenfield, Indiana, laboratories of Eli Lilly & Co. which treat wastes from animals raised for research purposes. All these plants are giving satisfactory performance. The approximate costs at each plant are estimated.

A short current article in Chemical and Engineering News, April 1970, describes Eli Lilly's new extensive treatment facility scheduled to commence operation in July 1970.

A full discussion of the new Eli Lilly plant at Clinton, Indiana, is found in "Waste control highlights plant design" in the November 1970 issue of Environmental Science and Technology. The philosophy and history of the plant's development are described, as well as the major processes used to handle wastes of various kinds. A complete flow chart shows all phases of waste handling, including statistics on temperatures and flow rates.

An article in the July 1970 issue of Drug and Cosmetic Industry describes the incineration system now used by G. D. Searle & Co. for disposal of solid wastes. The gas-fueled, three-stage system is described in detail, including quantities of waste presently processed, physical dimensions and makeup of the unit, and operating times and temperatures. Also included is a discussion of the unit's compliance with applicable noise and air pollution codes.

APPENDIX B

BIBLIOGRAPHY

APPENDIX B

BIBLIOGRAPHY - SOLID WASTE MANAGEMENT IN THE U.S. DRUG INDUSTRY

POLLUTION LITERATURE

Arbogast, C. C. Incineration of wastes from large pharmaceutical establishments. In Proceedings; 4th Industrial Waste Conference, Purdue University, 1945. p. 225-259.

Bloodgood, T. W. Treatment of animal wastes at the Greenfield Laboratories of Eli Lilly & Company. In Proceedings; 21st Industrial Waste Conference, Purdue University, 1966. p. 56-61.

Environment: maximum treatment. Chemical and Engineering News, 45(19):12, Apr. 1970.

Clift, M. A. Incinerating wastes from a large pharmaceutical establishment. Sewage Works Engineering, 19(1):21, 22, 24, Jan. 1948.

Waste disposal at Searle. Drug & Cosmetic Industry, p. 98-100, July 1970.

Reverse osmosis has potential in drug field. Drug Trade News, p. 31, Dec. 1969.

Waste control highlights plant design. Environmental Science & Technology, 4(11):898-900, Nov. 1970.

Friedman, J. H. Safe disposal of waste solids. Compost Science, p. 5-8, Autumn 1963.

Gabaccia, A. J. Composting waste sludge from pharmaceutical manufacturing. Sewage and Industrial Waste, 31(10):1175-1180, Oct. 1959.

Industry hiked pollution spending by 30% in 1969. Industrial Water Engineering, p. 31, Mar. 1970.

Knoedler, E. L. and S. H. Babcock, Jr. Pharmaceutical and biological plants. Industrial and Engineering Chemistry, 39(5):578-582, May 1948.

Mauriello, C. G. Industrial wastes operation--VI: biological and pharmaceutical wastes. Sewage and Industrial Wastes, 80(11): 1397-1398, Nov. 1958.

Molof, A. H. Pharmaceutical waste treatment by the trickling filter, actuated sludge, and compost processes. Biotechnology and Bioengineering, 1:197-209, 1962.

Reihard, D. G. Recovery of usable waste products. In Proceedings; 10th Sanitary Engineering Conference: Waste Disposal from Water and Wastewater Treatment Processes, University of Illinois, p. 99-104, Feb. 1968.

ECONOMIC LITERATURE

The U. S. market states where drug sales are highest per capita. Advertising Age, 32:59, Oct. 1961.

Rx drug sales by makers hit $3.1 billion in U. S. last year; up 13%. American Druggist, 154:32, Sept. 1967.

Wholesalers' share of Rx sales drops to 48%, PMA study finds. American Druggist, 156:32, Sept. 1967.

Blackman, J. Facts vs fancy regarding drug industry's economics. The Commercial and Financial Chronicle, 193:3, 30-31, Feb. 1961.

Barges, A. and B. R. Hickey. Drug industry profits. Financial Analysts Journal, 24:75-83, May 1968.

Drug industry: filling prescriptions under fire. Business Week, p. 140-154, Dec. 1960.

Where chemicals stand in changing economy. Chemical Week, 102(17): 28-33, Apr. 1968.

More R&D dollars for new drugs. Chemical Week, 100(15):18-19, Apr. 1967.

As drug sales climb. Chemical Week, 98(15):18-19, Apr. 1966.

Drugs get healthy. Chemical Week, 97:82, Sept. 1965.

Drugs: the glitter remains. Chemical Week, 96(15):47, Apr. 1965.

Drugs battle the profit squeeze. Chemical Week, 90(16):24, Apr. 1962.

Proud record - but problems ahead. Chemical Week, 84(20):35-36, May 1959.

In pharmaceutical earnings - an even better year. Chemical Week, 82(13):20-21, 37, Mar. 1958.

Connor, J. T. Research pharmaceuticals and the industry's growth. The Commercial and Financial Chronicle, 193:665, Feb. 1961.

De Haen, P. The impact of modern drugs on society and on the drug industry, Part One. Drug and Cosmetic Industry, 101:40-43, 171-176, Nov. 1967.

De Haen, P. The impact of modern drugs on society and on the drug industry, Part Two. Drug and Cosmetic Industry, 101:38-50, 52, 54, 56, 58, 172-176, Dec. 1967.

Ethical drug operations. Drug and Cosmetic Industry, 104:52-53, 149, Jan. 1969.

Prescription drug operations. Drug and Cosmetic Industry, 101:46-47, 168-169, Oct. 1967.

Drugs. Financial World, 113:7, Jan. 1960.

Health products. Forbes, 103:161-163, Jan. 1969.

Health products. Forbes, 97:103-105, Jan. 1966.

Drugs. Forbes, 95:83-85, Jan. 1965.

Drugs, Forbes, 93:60-61, 97, Jan. 1964.

Ethical drugs - dollars & druggists. Forbes, 81:79-80, 82 Jan. 1958.

Haroldson, R. H. S. 1958-59 Major reappraisal of chemicals and drugs. Magazine of Wall Street, 102:673-677, Aug. 1958.

Health News Institute. Facts about pharmacy and pharmaceuticals, 1968.

Johnson, P. Cosmetics field gets new look makes hay. Advertising Age. 32:57, Oct. 1961.

Kalish, J. Drug and cosmetic operations, 1968. Drug and Cosmetic Industry, 104:54, 56, 62, 164-167, May 1969.

Kalish, J. Drug and cosmetic operations, 1967. Drug and Cosmetic Industry, 102:56, Apr. 1968.

Kalish, J. Drug and cosmetic operations, 1966. Drug and Cosmetic Industry, 100:54, 56, 58, 169, May 1967.

Kalish, J. The drug industry - 1914-1964. Drug and Cosmetic Industry, 95:719-720, Nov. 1964.

The Drug Industry Quarterly Review. Laird Inc., Aug. 1970.

The Drug Industry Quarterly Review. Laird Inc., May 1970.

The Drug Industry Quarterly Review. Laird Inc., Nov. 1969.

The Drug Industry Quarterly Review. Laird Inc., Aug. 1969.

The Drug Industry Quarterly Review. Laird Inc., May 1969.

The Drug Industry Quarterly Review. Laird Inc., Nov. 1968.

The Drug Industry Quarterly Review. Laird Inc., Aug. 1968.

The Drug Industry Quarterly Review. Laird Inc., May 1968.

Reviews cover serious problems in chemical and pharmaceutical fields. National Underwriters, 189:7, Feb. 1966.

Drugs during 1965: a rise in profits, drop in products. Oil, Paint, and Drug Reporter, 189:7, Feb. 1966.

Medicinal chemicals: sales were up in 1964. Oil, Paint, and Drug Reporter. 188:40, Sept. 1965.

Drug taxes: $505 million. Oil, Paint, and Drug Reporter, 188:5, Aug. 1965.

U. S. to drug men: pay higher wage or stop selling. Oil, Paint, and Drug Reporter, 181:3, Jan. 1962.

Drug wage rate: surprise! unions are thinking big. Oil, Paint, and Drug Reporter, 180:3, Oct. 1961.

Drug industry wage poor. Oil, Paint, and Drug Reporter, 180:5, Sept. 1961.

Medicinals output in 1960: it was a pretty big dose. Oil, Paint, and Drug Reporter, 180:7, July 1961.

Drug research costs high in 1959. Oil, Paint, and Drug Reporter, 178:31, Aug. 1960.

Silberman, E. C. Drugs: the pace is getting furious. Fortune, 61:138, May 1960.

Spigelman, J. H. Technological and institutional transformation of the drug industry, Part I. Financial Analysts Journal, 22:113, Sept. 1966.

Technological and institutional transformation of the drug industry, Part II. Financial Analysts Journal, 22:21, Nov. 1966.

Stambovsky, L. The cost of drugs. Drug and Cosmetic Industry, 102:30, Feb. 1968.

Stanford Research Institute. The U. S. pharmaceutical industry. July 1965.

Stone, G. B. The ethical drug industry-a 20 year forward look. The Commercial and Financial Chronicle, 189:219, May 1959.

U. S. GOVERNMENT PUBLICATIONS

U. S. Bureau of the Census, Census of Manufactures, 1967. Drugs. Industry Series: MC67(2)-28C. Washington, U. S. Government Printing Office, 1970. 35 p.

U. S. Bureau of the Census, Census of Manufactures, 1967. Industry Series, Biological Products, SIC Code 2831, Preliminary Report. Washington, U. S. Government Printing Office, 1969. 4 p.

U. S. Bureau of the Census, 1967. Industry Series, Medicinals and Botanicals, SIC Code 2833, Preliminary Report. Washington, U. S. Government Printing Office, 1969. 4 p.

U. S. Bureau of the Census, Census of Manufactures, 1963. Industry Statistics: Drugs, MC63(2)-28C. Washington, U. S. Government Printing Office, 1966. 32 p.

U. S. Bureau of the Census, Census of Manufactures, 1963. Location of Manufacturing Plants by Industry, County, and Employment Size: Part 5 Chemical and Allied Products; Petroleum and Coal Products; Rubber and Plastic Products. Special Report MC63 (S)-35. U. S. Government Printing Office, Washington, D. C., 1966. 137 p.

U. S. Bureau of the Census, Current Industrial Reports, Pharmaceutical Preparations, Except Biologicals, 1967. Washington, U. S. Government Printing Office, 1968. 7 p.

U. S. Bureau of the Census, Current Industrial Reports, Pharmaceutical Preparations, Except Biologicals, 1966. Washington, U. S. Government Printing Office, 1967. 6 p.

U. S. Bureau of the Census, Current Industrial Reports, Pharmaceutical Preparations, Except Biologicals, 1965. Washington, U. S. Government Printing Office, 1967. 6 p.

U. S. Bureau of the Census, Current Industrial Reports, Pharmaceutical Preparations, Except Biologicals, 1964. Washington, U. S. Government Printing Office, 1965. 9 p.

U. S. Bureau of the Census, Current Industrial Reports, Pharmaceutical Preparations, Except Biologicals, 1963. Washington, U. S. Government Printing Office, 1964. 9 p.

U. S. Department of Health, Education and Welfare. National drug code directory. Prepared by Science Information Facility, Food and Drug Administration, October 1969. Washington, U. S. Government Printing Office, 1969. 347 p.

U. S. Department of Health, Education and Welfare. The drug makers and the drug distributors. Prepared by the Task Force on Prescription Drugs, December 1968. Washington, U. S. Government Printing Office, 1968. 86 p.

U. S. Department of Health, Education and Welfare. The drug users. Prepared by the Task Force on Prescription Drugs, December 1968. Washington, U. S. Government Printing Office, 1968. 145 p.

U. S. Department of Health, Education and Welfare. The drug prescribers. Prepared by the Task Force on Prescription Drugs, December 1968. Washington, U. S. Government Printing Office, 1968. 50 p.

U. S. Department of Health, Education and Welfare. Current american and foreign programs. Prepared by the Task Force on Prescription Drugs, December 1968. Washington, U. S. Government Printing Office, 1968. 205 p.

PHARMACEUTICAL COMPANY AND ASSOCIATION LITERATURE

Cousins, Walter, ed. Drug topics red book 1969. New York, Topics Publishing Co., Inc., 1968. 584 p.

Cousins, Walter, ed. Drug topics red book, cumulative supplement No. 2, May 1969. New York, Topics Publishing Co., Inc., 1969. 128 p.

Pharmaceutical Manufacturers Association. Prescription drug industry fact book. 3d ed. Washington, May 1968.

OTHER LITERATURE

Tighter rein on drug testing. Business Week, p. 75, Jan. 1963.

FDA turns to the barnyard. Chemical Week, 102:33, Apr. 1968.

Tablet packaging. Drug and Cosmetic Industry. 104:112, Mar. 1969.

Plastic bottle seminar. Drug and Cosmetic Industry, 104:80, Apr. 1969.

A seminar on unit dose packaging. Drug and Cosmetic Industry, 104:80, May 1969.

Johnson, J. L. Quality control-oral and other non-sterile dosage forms. Drug and Cosmetic Industry, 99:50, Sept. 1966.

Latourette, W. I. Animal medicines. Barrons, 38:11, July 1958.

Meyers, E. L. Master-formula and batch-production records. Drug and Cosmetic Industry, 99:70, Dec. 1966.

Peller, M. L. and J. Rosenthal. Trends in R&D manpower in the pharmaceutical industry 1959-65 and 1968. Public Health Service Publication No. 1443, Washington, U. S. Government Printing Office, Mar. 1966.

Smith, M. C. The problems of economic and market research in the pharmaceutical industry: an application of the census of manufactures. Doctoral dissertation, The University of Mississippi, Aug. 1964.

Smith M. C., R. Bennett, and C. W. Hartman. The census of manufactures as a gauge of drug industry growth. Drug and Cosmetic Industry, Oct. 1967.

The pharmaceutical industry-its location pattern. Journal of the American Pharmaceutical Association, N57(4):185, Apr. 1967.

U. S. Department of Commerce. Earning in manufacture of drugs and medicine. Washington, U. S. Government Printing Office, Mar. 1961.

Varsano, J. Pharmaceuticals in plastic packaging, Part I. Drug & Cosmetic Industry, 104:88, Jan 1969.

Pharmaceuticals in plastic packaging, Part II. Drug & Cosmetic Industry, 104:72, Feb. 1969.

Pharmaceuticals in plastic packaging, Part III. Drug & Cosmetic Industry, 104:98, Mar. 1969.

Wallace, P. Employment patterns in the drug industry, 1966. U. S. Department of Commerce. Washington, U. S. Government Printing Office, Sept. 1967.

APPENDIX C

QUESTIONNAIRE

NATIONAL INDUSTRIAL SOLID WASTE MANAGEMENT STUDY--DRUG INDUSTRY

DEFINITIONS

1. SIC 2831--Biological Products:

   Establishments primarily engaged in the production of bacterial and virus vaccine, toxoids, and analogous products (such as allergenic extracts), serums, plasmas, and other blood derivatives for human or veterinary use.

2. SIC 2833--Medicinal Chemicals and Botanical Products:

   Establishments primarily engaged in (1) manufacturing bulk organic and inorganic chemicals and their derivatives; and (2) processing (grading, grinding, and milling) bulk botanical drugs and herbs. Establishments primarily engaged in manufacturing agar-agar and similar products of natural origin, endocrine products, manufacturing or isolating basic vitamins, and isolating active medicinal principals such as alkaloids from botanical drugs and herbs are also included in this industry.

3. SIC 2834--Pharmaceutical Preparations:

   Establishments primarily engaged in manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use. The greater part of the product of these establishments are finished in the form intended for final consumption, such as ampoules, tablets, capsules, ointments, medicinal powders, solutions, and suspensions. Products of this industry consist of two important lines, namely: (1) pharmaceutical preparations promoted primarily to the dental, medical, or veterinary professions: and (2) pharmaceutical preparations promoted primarily to the public.

Budget Bureau No. 85-S-68-014
Approval Expires March 31,1971

NATIONAL STUDY OF SOLID WASTE MANAGEMENT IN THE DRUG INDUSTRY

PART I. LOCATION AND ADJACENT COMMUNITY

1. In which of the following geographic regions is this plant located? (Please check one only below)

A. NEW ENGLAND	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont	☐
B. MIDDLE ATLANTIC	New Jersey, New York, Pennsylvania	☐
C. SOUTH ATLANTIC	Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia	☐
D. EAST NORTH CENTRAL	Illinois, Indiana, Michigan, Ohio, Wisconsin	☐
E. EAST SOUTH CENTRAL	Alabama, Kentucky, Mississippi, Tennessee	☐
F. WEST SOUTH CENTRAL	Arkansas, Louisiana, Oklahoma, Texas	☐
G. WEST NORTH CENTRAL	Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota	☐
H. MOUNTAIN	Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming	☐
I. PACIFIC	Alaska, California, Hawaii, Oregon, Washington	☐

2a. In the immediate vicinity of this plant (a one-mile radius), which of the following items best describes the economic classification of the area? (Please check all that apply)

☐ Agricultural ☐ Industrial ☐ Commercial
☐ Residential ☐ Other (Describe) _____
_____
_____

Interview No. 85

2b. What is the approximate distance to the nearest residential area from this plant?

☐ Less than 1 mile ☐ 1 mile to 5 miles ☐ More than 5 miles

2c. What is the approximate distance to the nearest city, town or village from this plant?

☐ less than 1 mile ☐ 1 mile to 5 miles ☐ More than 5 miles

PART II. PLANT CLASSIFICATION DATA

1. Which of the following manufacturing processes are conducted at this plant?

☐ Packaging	☐ Mixing	☐ Synthesis
☐ Capsuling	☐ Grinding	☐ Tableting
☐ Fermentation	☐ Extractions	
☐ Other (Please specify)	_____	_____
	_____	_____

2. Please classify this plant in terms of the product categories listed below based on value of shipments including inter-plant transfer. (List percentages in appropriate box.)

SIC		Percent (%) of Total Value of Shipment
2831	Biological Products	_____
2833	Medicinal Chemicals and Botanical Products	_____
2834	Pharmaceutical Preparations	_____
____	Other (describe) _____	

3a. List total number of employees working at this plant as of _____ (date)

1970 _____.

Categories

86

Administrative ____

Sales ____

Research ____

Production ____

Production Control ____

3b. List the approximate number of production employees working primarily in each product category.

2831 Biological Products _____

2833 Medicinal Chemicals and Botanical Products _____

2834 Pharmaceutical Preparations _____

_____Other (as described in number two) _____

_____

_____

4. What was sales dollar value of all shipments from this plant (including inter-plant transfer) during 1969?

☐ Less than $499,999
☐ $500,00 to $999,999
☐ $1,000,000 to $4,999,999
☐ $5,999,999 to $9,999,999
☐ $10,000,000 to $49,999,999
☐ $50,000,000 or more

PART III. PRODUCTION DATA

1. During 1970, do you expect production levels to be at least 25% higher, substantially lower, or approximately the same as 1969 levels? (Please check one only below)

☐ 25% or more higher
☐ 25% or more lower
☐ Less than 25% difference

2. Have any changes been made in processes, processing procedures, and/or packaging within the <u>past twelve months</u> that have significantly affected solid waste generation at this plant?

☐ Yes ☐ No

If yes - - ☐ Increase or ☐ Decrease

If yes, describe in what way and to what extent (as a percent (%) of your 1969 waste generation quantities _____

_____

_____

3. Do you expect any processing and/or packaging changes within the next twelve months that may significantly affect solid waste at this plant?

☐ Yes ☐ No

If yes, describe in what way and to what extent (as a percent (%) of your 1969 waste generation quantities) _____

☐ Increase ☐ Decrease

_____

_____

4. What are your operating periods for this plant? (Check all that apply)

PRODUCTS IN SIC 2831	PRODUCTS IN SIC 2833	PRODUCTS IN SIC 2834	OTHER PRODUCTS *
☐ 5 days/wk	☐ 5 days/wk	☐ 5 days/wk	☐ 5 days/wk
☐ 7 days/wk	☐ 7 days/wk	☐ 7 days/wk	☐ 7 days/wk
☐ 1 shift/day	☐ 1 shift/day	☐ 1 shift/day	☐ 1 shift/day
☐ 2 shifts/day	☐ 2 shifts/day	☐ 2 shifts/day	☐ 2 shifts/day
☐ 3 shifts/day	☐ 3 shifts/day	☐ 3 shifts/day	☐ 3 shifts/day
☐ Not applicable	☐ Not applicable	☐ Not applicable	☐ Not applicable

Other _____

_____

_____

_____

* As described in question No.2 , Part II

PART IV. SOURCES AND DESCRIPTION OF SOLID WASTE MATERIAL

For each SIC Product Group listed below, please describe the nature of all solid wastes (e.g., paper, plastic, waste drugs, dead animals, etc.) which are generated at this plant.

DESCRIPTION OF WASTE MATERIALS GENERATED				
SIC 2831 Biological Products	SIC 2833 Medicinal Chemicals and Botanical Prod.	SIC 2834 Pharmaceutical Preparations	OTHER Non-Production Activities	OTHER Products Groups

☐ Not Applicable ☐ Not Applicable ☐ Not Applicable ☐ Not Applicable ☐ Not Applicable

PART V. TYPES OF SOLID WASTE GENERATED

1. Please check whether the wastes listed below (a - i) are generated at this location.
2. If any of these wastes do exist at your plant, please indicate the following in the table below:
   a. Average quantity and units of waste.
   b. The time period it takes for the reported quantity of waste to be generated.
   c. Whether these quantities are estimated or actually measured.

TYPES OF WASTE	DESCRIPTION	GENERATED YES	GENERATED NO	QUANTITY (NUMBERS)	ARE QUANTITIES EST.	ARE QUANTITIES ACTUAL
a. Garbage	Waste from food; cafeteria waste; waste from handling or storage of foods; etc.	☐	☐	_____ ☐ pounds/day ☐ tons/month	☐	☐
b. Rubbish	Containers, cartons; plastics; wood; excelsior; bedding; tin cans; glass; crockery; scrap metals; labels and other waste materials; rags; miscellaneous office wastes; vending machine wastes.	☐	☐	_____ ☐ pounds/day ☐ tons/month	☐	☐
c. Ashes	Residue from on-site incineration, cinders from combustion of coal, etc.	☐	☐	_____ ☐ pounds/day ☐ tons/month	☐	☐
d. Street Refuse	Sweepings; leaves; contents of litter receptacles, etc.	☐	☐	_____ ☐ pounds/day ☐ tons/month	☐	☐
e. Dead Animals	Any laboratory animal.	☐	☐	_____ ☐ pounds/day ☐ tons/month	☐	☐
f. Production Wastes Classified as Solids	Waste biologic material; eggs; discarded microbial masses; waste drug materials; dusts, diatomaceous earth and fillers; waste solid chemicals; etc.	☐	☐	_____ ☐ pounds/day ☐ tons/month	☐	☐
g. Sewage Solids	Solids from on-site treatment of sewage.	☐	☐	_____ ☐ pounds/day ☐ tons/month	☐	☐
h. Manures		☐	☐	_____ ☐ pounds/day ☐ tons/month	☐	☐
i. Other Solid Waste Materials	(Please describe)_____ _____	☐	☐	_____ ☐ pounds/day ☐ tons/month	☐	☐

PART VI. METHODS OF SOLID WASTE DISPOSAL

1. Under column 2, for each type of waste, please record the percent accounted for by each type of disposal method.

2. For each type of waste produced, please record under column 3 the percent accounted for by each type of hauling or collection.

(1) TYPE OF WASTE	(2) METHOD OF DISPOSAL (State % disposed by each method)									(3) HAULED BY (State % of each)			(4) Coll'n Frequency
	Land Fill %	Spread on Land %	Incineration %	Animal Feed %	Salvage %	Hauled from Premise %	Composting %	OTHER SPECIFY METHOD %		Self %	Private Collector %	Public Collector %	Times per Week
Total													
a. Garbage													
b. Rubbish													
c. Ashes													
d. Street Refuse													
e. Dead Animals													
f. Production wastes classified as solids													
g. Sewage solids													
h. Manures													
i. Other solid waste materials *(Please describe)*													

PART VII. GENERAL INFORMATION

1a. At this plant, are solid waste materials pretreated before disposal or removal?

☐ Yes . . . In what manner?

_____

_____

_____

_____

_____

☐ No

1b. Are waste materials sorted at your plant prior to disposal or removal?

☐ Yes ☐ No

2a. What specific types of mechanical equipment do you use to move solid waste at this plant? (Please record below and describe)

Type of Equipment	Description
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

PART VII. ON-SITE WASTE FACILITIES

2b. Please record below the following information with respect to ultimate disposal (disposal, collection, and/or storage), facilities at your location used for solid waste.

A. Description of Facility (Incinerators, trucks, containers, loaders, landfills, tractors, compactors shredders)

B. Year of Installation

Facility	(A) Description	(B) Year Facility Installed
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
	93	

3. By which of the following methods are solid waste materials removed from your plant?

☐ Own company resources ☐ Outside contractor

☐ Municipal or government

Comment: _____

4a. To what extent is a governmental agency (local, municipal, state, etc.) involved in the specifications for waste removal from your facility? (Please be as specific as possible)

_____

_____

_____

4b. Which planning agencies include your solid wastes as part of their comprehensive planning? (Check all appropriate categories.)

☐ No Agency ☐ Local ☐ County ☐ State ☐ Regional

5a. What specific types of treatment are utilized in the handling of explosive or radioactive solid wastes if any such wastes are generated at this plant?

_____

_____

_____

_____

5b. What specific <u>safety</u> procedures are followed in handling hazardous solid waste?

_____

_____

_____

6. Approximately what percent of your total cost for solid waste management is accounted for by each of the following factors?

Factor	Percent of Cost
Collection	
At point of origin	_____%
At intermediate points	_____%
Haul to final disposition or treatment.	_____%

Storage at or near origin . . . . . _____%

Pre-treatment . . . . . _____%

In-house disposal or treatment . . . . . _____%

Off-plant site disposal or treatment . . . . . _____%

Other . . . . . .

_____ _____%

_____ _____%

_____ _____%

PART VIII. ADDITIONAL INFORMATION ON SOLID WASTE DISPOSAL--ON-SITE HANDLING

1. Is any solid waste material discharged from the plant with the liquid waste effluent?

☐ Yes . . . . Please answer questions 2a,2b, 2c.
☐ No . . . . Please skip to question 3

2a. Is the solid waste material that is discharged with the liquid effluent: (Please record all methods used)

☐ discharged without treatment? ☐ discharged after comminution? ☐ discharged in other manner(describe)

2b. Which are the most usual methods of disposing of such solid waste materials?

_____

_____

_____

2c. What places or methods are used for disposing of liquids that contain solid materials? (Please check all that apply)

☐ Stream,lake,ocean,bay ☐ Irrigation
☐ Sewage treatment plant ☐ Other _____
Lagoon,pond

3. Are on-site facilities provided for solid-liquid separation ?

☐ Yes . . .Please answer questions 4a,4b.
☐ No . . .Please skip to question 5.

4a. What methods are used for solid-liquid separation?

☐ Screening
☐ Other (Please describe)

_____

_____

_____

4b. If screens are employed, please circle all that apply under types and mesh.

TYPES	STATIC	VIBRATING	REVOLVING	MESH BELT	OTHER
	Mesh	Mesh	Mesh	Mesh	Mesh
	10	10	10	10	10
	20	20	20	20	20
	30	30	30	30	30
	40	40	40	40	40
	50	50	50	50	50

5. What methods are used for accumulating and storing solid waste materials to be hauled from the plant?

☐ Barrels, bins
☐ Permanent hopper
☐ Other . . . please specify

_____

_____

_____

6. What are the annual out-of-pocket expenses for each type of solid waste hauling listed below?

	COSTS
COLLECTION	
In Plant Production	
In Plant Other (janitorial, gardening, housekeeping, construction). . .	
DISPOSAL	
In Plant	
Removal from Plant	
Total	_____

PART IX. INCINERATION

1. Is incineration conducted at this plant?

☐ Yes . . . . Please answer questions 2 and 3
☐ No. . . . . Please skip to part X

2. Does the incinerator function:

☐ Continuously?
☐ Periodically? _____
please specify

3a. Which of the following types of incineration systems do you use for the disposal of solid wastes?
(please check below)

Type of incineration	Use	
	yes	no
Batch feed	☐	☐
Continuous feed . .	☐	☐

3b. Do you use supplementary fuel?

☐ Yes . . . . .What types?

_____

_____

☐ No

3c. What special incineration processes are used at this plant? (fluid bed, water wall, refractory, etc.)

_____

_____

_____

PART X. DISPOSAL SITE INFORMATION --- LAND FILL

1. What is the distance from your plant to the land fill site?_____miles.

2. How would you describe the land fill site?

☐ Quarry,pit
☐ Gully,canyon
☐ Level ground
☐ Marsh,tideland
☐ Other-
_____

3. Approximately how many acres comprise the fill site? _____acres.

4. Is this site owned by: (please check one)
☐ Your Company? ☐ Another private concern
☐ Public site? ☐ Other _____
please specify

5. Is this site operated by: (please check one)
☐ Your Company ☐ Another private concern?
☐ Public operation? ☐ Other - _____
please specify

6. Which of the following types of waste are disposed of at this site (please check all that apply).
☐ Waste from your plant only
☐ Municipal waste ☐ Other _____
☐ Industrial waste ☐ No knowledge

7. How many tons/pounds of waste per year does your plant discharge at the land fill site?
_____ tons
OR
_____pounds

comments: _____

8. What is the frequency of covering the waste?
☐ Immediately after discharge
☐ Once a day
☐ Other _____

9. Is open burning practiced at this site?
☐ Yes ☐ No

10. Which of the following environmental problems occur at the land fill site.
☐ Insects
☐ Rodents
☐ Odors
Other: please specify
_____
_____

PART XI. DISPOSAL SITE INFORMATION --- SPREAD ON LAND
(Distribute on surface of land area or incorporate in surface layers of soil).

1. What is the distance from your plant to the disposal site?_____miles.

2. How would you describe the land used for waste disposal?
   - ☐ Agricultural
   - ☐ Wasteland
   - ☐ Other - describe

3. What is the approximate size of this area? _____ acres.

4. Is the land owned by:
   ☐ Your Company? ☐ Another private concern ☐ Public Site?
   ☐ Other _____.

5. How many tons/pounds of waste does your plant spread on land at this site daily?
   _____ tons OR _____ pounds

6a. Is waste covered?
   ☐ Yes ☐ No

6b. If covered, what is the frequency of covering the waste?
   ☐ Immediately ☐ Once a day ☐ Once a week ☐ Other _____

7. What are the methods used to cover or incorporate in the soil any wastes which are spread on land?
   (Please check all that apply)
   - ☐ Cover with top soil
   - ☐ Discing into soil
   - ☐ Trenching
   - ☐ Other (please describe)

   _____

8. Which of the following environmental problems occur at this site?
   ☐ Insects ☐ Rodents ☐ Odors ☐ Other: _____
   please specify

PART XII. DISPOSAL SITE INFORMATION --- OTHER METHODS

1. Excluding the previously discussed methods, what other disposal methods (e.g. composting, etc.) are primarily used by your company?

   _____

   _____

   _____

   Please answer questions 2 through 6 for the disposal method indicated above.

2. What is the distance from your plant to this disposal site? _____ miles.

3. Is this site owned by
   ☐ Your company? ☐ Another private concern? ☐ Public site ?
   ☐ Other _____

4. Is this site operated by:

☐ Your company? ☐ Another private concern? ☐ Public site?

☐ Other _____

5. For which of the following types of waste is this site used?

☐ Waste from this plant only ☐ Domestic refuse other than garbage

☐ Garbage

☐ Industrial refuse ☐ Other _____

6. Please comment on any other waste disposal methods used by your plant.

_____

_____

_____

PART XIII. SALVAGE OR RE-USE

1a. Are any of the types of waste listed in column 1a below salvaged at this plant? (Please check in column 1b)

1a	1b			
Type of Waste	Salvaged		Used as By-Product	
	yes	no	yes	no
Production Solid Wastes.	☐	☐	☐	☐
Containers or Packaging Materials	☐	☐	☐	☐

2a. If waste is salvaged, is this accomplished by your company or another firm? (please check below)

☐ Own company ☐ Another firm

2b. Is the production of by-products from solid waste accomplished by your company or another firm?

☐ Own company ☐ Another firm

3. Please list and describe below the by products produced from the solid waste.

_____

_____

_____

_____

_____

_____

_____

4a. Are there any economic or georgraphical limitations affecting salvage or re-use of the solid wastes generated by this plant?

☐ Yes . . . .Please go to question 4b

☐ No . . . .Please skip to Part XIV

4b. Specifically, what are the economic or geographical limitations affecting salvage or re-use of solid wastes generated by this plant?

_____

_____

_____

_____

_____

_____

_____

PART XIV. THE NEXT FIVE YEARS

1. Please think now of the time period covering the next five years. During this period, would you expect the overall quantities of solid waste materials generated at your plant to:

☐ Increase? ☐ Decrease? ☐ Remain about the same?

2. Do you expect to revise any of your solid waste management practices?

☐ Yes . . .In what way? _____

_____

_____

☐ No

3. Do you expect to have any <u>additional</u> types of solid wastes which are not produced at this time?

☐ Yes . . .describe _____

_____

_____

☐ No

4. Again, looking ahead, do you expect your <u>costs</u> for the management of solid wastes to: (please check one only).

☐ Increase?
☐ Decrease?
☐ Remain the same?

→ Why do you say this? _____

_____

_____

PART XV. PREPARATION OF THIS QUESTIONNAIRE

1. Which of the following departments and/or activities of your firm participated in the preparation of this questionnaire? (please check all that apply).

- ☐ Management
- ☐ Production
- ☐ Engineering
- ☐ Marketing
- ☐ Financial
- ☐ Other _____
  please specify

THANK YOU FOR YOUR COOPERATION